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PROVISIONAL SPECIFICATION

Invention Title: **Improved Transcutaneous Power and Data Transceiver System**

The invention is described in the following statement:

Our Ref: 031037

IMPROVED TRANSCUTANEOUS POWER AND DATA TRANSCEIVER SYSTEM

Field of Invention

The present invention relates to a device and/or a system which is capable of transmitting and/or receiving power and data through the skin or epidermal layer of a patient to an implanted medical device within the body of the patient.

Background

Many advances in medical technology require the use of implantable medical devices to aid, assist or supplement the normal bodily function of a patient.

Implantable medical devices can be distinguished into two major categories. These categories are: active devices, which are devices that actively assist the patient's body and passive devices, which passively assist the patient. Active devices typically require a power source or supply, whilst passive devices typically do not require such a power or supply source.

An example of an active medical device is an implantable blood pump which actively pumps blood throughout a patient's circulatory system. For an implantable blood pump to function the blood pump needs a suitable power supply. It also generally may also require a controller supply and receiver data, power and instructions to the implanted portion of the pump.

In the past, a percutaneous lead has been used to convey instructions, and other electrical signals, data and power to and from an implantable device. Typically, such a lead would require perforation of the patient's skin layer so as to allow the lead to pass through the skin. These leads usually incorporate features in which the lead may to some extent bond or integrate internally with the patient's body. There are many disadvantages with this type of system. One of the largest of these

disadvantages is that it creates a site on the patient's skin which is open to infection for long periods of time.

As a result, there has been a long felt need for an improved arrangement that conveys power, data and/or other electrical signals to and from an implantable medical device through the skin layer of a patient. It is an object of the present invention to address or ameliorate at least one of the above disadvantages.

Brief description of the invention

Accordingly, in one broad form of the invention there is provided a device for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient; said device including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element so as to permit the transmission of an electro-magnetic signal by transcutaneous electro-magnetic coupling between said first element, said core and said second element, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally within said patient.

Preferably said first element can transmit or receive an electro-magnetic signal.

Preferably said second element can transmit or receive an electro-magnetic signal.

Preferably said electric signal including data information and/or power.

Preferably said core including a plurality of portions.

Preferably said transmission is from direct current to direct current.

Preferably said first element comprises at least a length of wire.

Preferably said second element comprises at least a length of wire.

Preferably said wire forms a coil around at least one portion.

Preferably said wire includes polyurethane coated copper litz wire.

Preferably said first element in a generally ring shaped configuration.

Preferably said second element is coiled around the core.

Preferably said at least one portion of said core pierces the skin layer of patient.

Preferably no portion of said core pierces the skin layer of patient.

Preferably said core forms a generally continuous loop.

Preferably said core forms a continuous shape generally in rectangular or square configuration.

Preferably said core generates a relatively small amount of amount magnetic flux leakage.

Preferably said device has a transmission efficiency in the range of 70% to 90%.

Preferably said device is connected to at least one controller and/or rectifier.

Preferably a portion of the device external to the patient's body is encased in a socket arrangement.

Preferably said device cooperates with a blood pump.

Preferably said blood pump is a centrifugal type pump.

Preferably said pump includes an impeller.

Preferably said impeller is hydrodynamically suspended.

Preferably the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

Preferably the first element is secured in place by at least one clip.

Preferably said device is adapted for relatively long term use.

Preferably said long term use is of a period greater than 1 week.

Preferably said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

In a further broad form of the invention there is provided a system for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient; said device including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element so as to permit the transmission of an electro-magnetic signal by transcutaneous electro-magnetic coupling between said first element, said core and said second element and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally within said patient.

Preferably said first element can transmit or receive an electro-magnetic signal.

Preferably said second element can transmit or receive an electro-magnetic signal.

Preferably said electro-magnetic signal including data information and/or power.

Preferably said core includes a plurality of portions.

Preferably said transmission is from direct current to direct current.

Preferably said first element comprises at least a length of wire.

Preferably said second element comprises at least a length of wire.

Preferably said wire forms a coil around at least one portion.

Preferably said wire includes polyurethane coated copper litz wire.

Preferably said first element in a generally ring shaped configuration.

Preferably said second element is coiled around the core.

Preferably said at least one portion of said core pierces the skin layer of patient.

Preferably said no portion of said core pierces the skin layer of patient.

Preferably said core forms a generally continuous loop.

Preferably said core forms a continuous shape generally in rectangular or square configuration.

Preferably said generates a relatively small amount of amount magnetic flux leakage.

Preferably the transmission efficiency of the device is in the range of 70% to 90%.

Preferably said device is connected to at least one controller and/or rectifier.

Preferably a portion of the device external to the patient's body is encased in a socket arrangement.

Preferably said device cooperates with a blood pump.

Preferably said blood pump is a centrifugal type pump.

Preferably said pump includes an impeller.

Preferably said impeller is hydrodynamically suspended.

Preferably the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

Preferably the first element is secured in place by at least one clip.

Preferably said device is adapted for relatively long term use.

Preferably said long term use is of a period greater than 1 week.

Preferably said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

In yet a further broad form of the invention there is provided a method for transmission of an electro-magnetic signal to an active implanted medical device across the skin layer of a patient including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient.

Preferably said first element can transmit or receive an electric signal.

Preferably said second element can transmit or receive an electric signal.

Preferably said electric signal includes data information and/or power.

Preferably said core includes a plurality of portions.

Preferably said transmission is from direct current to direct current.

Preferably said first element comprises at least a length of wire.

Preferably said second element comprises at least a length of wire.

Preferably said wire forms a coil around at least one portion.

Preferably said wire includes polyurethane coated copper litz wire.

Preferably said first element in a generally ring shaped configuration.

Preferably said second element is coiled around the core.

Preferably said at least one portion of said core pierces the skin layer of patient.

Preferably no portion of said core pierces the skin layer of patient.

Preferably said core forms a generally continuous loop.

Preferably said core forms a continuous shape generally in rectangular or square configuration.

Preferably said core generates a relatively small amount of amount magnetic flux leakage.

Preferably the transmission efficiency of the device is in the range of 70% to 90%.

Preferably said device is connected to at least one controller and/or rectifier.

Preferably a portion of the device external to the patient's body is encased in a socket arrangement.

Preferably said device cooperates with a blood pump.

Preferably said blood pump is a centrifugal type pump.

Preferably said pump includes an impeller

Preferably said impeller is hydrodynamically suspended.

Preferably the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

Preferably the first element is secured in place by at least one clip.

Preferably said device is adapted for relatively long term use.

Preferably said long term use is of a period greater than 1 week.

Preferably said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

Preferably said core forms a flux loop and said core is formed of at least one magnetic portion.

Preferably said skin layer is a closed skin layer.

Preferably said core forms a flux loop and said core is formed of at least one magnetic portion.

Preferably said skin layer is a closed skin layer.

In yet a further broad form of the invention there is provided a method for implanting a device; wherein said device is capable transmission of an electro-magnetic signal to an active implanted medical device across the skin layer of a patient and comprises a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient; and wherein said method includes:

i) making a incision in a skin layer of a patient;

ii) inserting said core partially into said incision; and

iii) closing said incision;

Preferably said incision is closed by stitching.

In yet a further broad form of the invention there is provided a method for implanting a device; wherein said device is capable of transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient and comprises a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally to said patient; and wherein said method includes:

i) making a series of incisions in a skin layer of said patient;

ii) inserting said core partially into said incision

iii) covering and sealing said core with a skin layer; and

iv) closing and sealing said incision.

Preferably closing and sealing is achieved by stitching.

In yet a further broad form of the invention there is provided a device for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by transcutaneous electo-magnetic coupling, in use, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient and wherein said device includes a series of interlocking rings.

Preferably said device is implanted in skin layer near, adjacent, about or proximal to a site on the earlobe of a patient.

Brief description of the drawings

Embodiments of the present invention will now be described with reference to the accompanying drawings wherein:

Figure 1 is a cross sectional view of a first preferred embodiment of the present invention;

Figure 2 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 3 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 4 is a schematic layout of an embodiment;

Figure 5 is top view of a site for implantation of a further embodiment occurring on a patient;

Figure 6 is top view of a site for implantation of a further embodiment occurring on a patient;

Figure 7 is cross sectional view of part of a further embodiment;

Figure 8 is an isometric view of a preferred impeller of part of a further embodiment;

Figure 9 is an isometric view of a further preferred impeller of part of a further embodiment;

Figure 10 is a cross sectional view of a patient showing partial implantation of an embodiment;

Figure 11 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 12 is a side view of a further preferred embodiment of the present invention;

Figure 13 is a cross sectional view of the embodiment shown in figure 13;

Figure 14 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 15 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 16 is a cross sectional view of a further preferred embodiment of the present invention;

Figure 17 is a cross sectional view of a further preferred embodiment of the present invention; and

Figure 18 is a cross sectional view of a further preferred embodiment of the present invention;

Detailed Description of the Preferred Embodiments

Figure 1 shows a first preferred embodiment of the present invention. A Transcutaneous Power and/or Data Transceiver System ('TPDTS') 41 is shown. This embodiment comprises an electrically conductive core 2 which in this embodiment is in a circular configuration. However it may be noted that many configurations may be used so long as the core aids in the return of magnetic flux. Preferably, this core may form a loop of any shape or configuration.

The electrically conductive core 2 may be partially inserted in the skin layer 1 of a patient. During implantation it is envisaged that this core 2 may extend partially from the skin layer at points 6. Where the magnetic core 2 extends past point 6 a layer of skin may be wrapped around the core to effectively seal the core from the outside environment 144. Please note that other methods of sealing are possible. The layer of skin that seals the core 2 forms barrier 45. Preferably, this configuration or a similar arrangement of the TPDTS may form an air gap 5. The core 2 may also be shaped into a square, circle, oval, rectangle and may still function in the desired or preferred manner. The covering forming the barrier 45 may be constructed from the patient's skin, wherein the skin is wrapped around the core and separating the core from the outside environment 144 by stitching. After some time the wound at the point of insertion will heal and seal the coil from the outside environment 44.

Preferably, coiled around the core 2 within the body of the patient is an internal coil 4 which is in turn connected to wires 7. The wires 7 may be connected to an internal controller, internal battery and/or an implantable active medical device.

Preferably, when in use, a wire 3 is threaded from the outside of the patient around the core 2 and the barrier 45 through the air gap 5. This wire 3 may also be wrapped once or several times around the conductive core 2 and the barrier 45 to form a loose coil. The wire 3 may be then connected to a controller or external power device.

When in operation, an electrical signal may be delivered through wire 3. The electrical signal in wire 3 generates an electromagnetic force radially from the surface of the wire 3. At the point where core 2 cuts the electromagnetic force, signal or current generated by wire 3, a force, signal or current is generated within the core 2. The core 2 then passes this force, signal or current to coil 4. An electrical signal is then generated in coil 4, which mirrors the original electrical signal transmitted from wire 3. Coil 4 may then pass the electrical signal to an internal controller, a rectifier, an internal battery or other implantable active medical devices.

The electrical signal may be preferably transmitted and received by either coil 4 or wire 3. Thus preferably, this arrangement may allow two way flow of electrical signals from coil 4 to wire 3 or from wire 3 to coil 4. This electrical signal may be transmitted and/or received as full duplex or half duplex signal.

Preferably a Direct Current (DC) rectifier or multiple rectifiers may be added to the embodiment shown in figure 1. These rectifiers may be added to rectify the electrical signal received and/or transmitted by wire 3 and/or wire 7.

Preferably, the core 2 may be constructed of a ferro-magnetic material encased in a biocompatible material. Preferably this material may also be wear resistant and/or rigid. Preferably, Titanium Nitride may be used to encase the core 2. Alternatively, the core 2 may also be encased in a polymer that possesses the desired qualities.

The core 2 may also be rigid to support the formation of the gap 5 and may also serve to minimise wear by the patient when in use. However, in some circumstances it may be beneficial to use a core that is flexible.

The internal coil 4 may also be encased in a biocompatible material to limit the chance of side reactions with the patient's body. This biomaterial material may be teflon, velour or a similar material.

Also preferably, the surfaces around the air gap 5 may be reinforced to prevent breakage of the device or damage to the patient. This is especially relevant in cases where the device is expected to be implanted for long term use. The reinforcing material may be placed over the barrier 45 or over the magnetic core 2. This reinforcing material may be a polymer, metal (for example titanium), Kevlar™ or similar material.

The wire 3 may also be wrapped around the barrier 45 multiple times. This wrapping of wire 3 may increase the efficiency the magnetic coupling between the wire 3 and the core 2.

Preferably a polyurethane coated copper litz wire may be used for any windings around the core or any portion thereof. The term litz is derived from the German word 'litzendraht' meaning woven wire. Litz wire may be generally constructed of individual film insulated wires bunched or braided together in a uniform pattern of twists and length of lay. The multi-strand configuration minimises the power losses otherwise encountered in comparable solid conductors or the tendency of radio frequency current to be concentrated at the surface of the conductor. Litz wire may overcome this problem by increasing the surface area of the length of wire without significantly increasing the general size of the conductor.

This embodiment of the present invention may be used with any active implantable medical devices. Examples of these devices include but are not limited to: rotary blood pumps, heart pumps, left ventricle assist device, active implantable diagnostic equipment, aural implants, miniaturised pump devices, ocular implants and other implantable devices.

Additionally, it should be noted that the distance between wire 3 and core 2 should be minimised to increase magnetic efficiency. Preferably the efficiency of this embodiment may be in the range of 70%-90% which is a significant improvement over more traditional forms of transcutaneous energy transmission systems. Efficiency of the system or device may increase if the core is continuous in structure, for example, as illustrated in figure 1.

This embodiment may also be able to transmit and/or receive an electrical signal across the skin barrier of a patient without the need for a permanent opening in the skin of the patient. The signal may preferably include a power transmission and/or data information relating to the control and regulation of the implanted medical device for which it is to be attached. Additionally, the data information may include software controller upgrades, data regarding patient health and status of the medical device. Preferably, control or regulation data may be transmitted into the body of a patient and medical device status data may be transmitted from within the patient to external devices such as external controllers and/or personal computers.

A further embodiment is shown in figure 2. This embodiment shows an alternate preferred version of a TPDTS 42. In the embodiment of figure 2, an electrically conductive core 10 is inserted within a skin layer 11. In this preferred embodiment, the core is a generally C-shaped device including a small air gap 13.

The core 10 of this embodiment is preferably flexible which allows movement of the core 10. Where the core 10 extends beyond the point at which the patient's normal skin layer would have been without this device, a barrier 28 encases the otherwise exposed core 10. This barrier is preferably constructed of skin material taken from the patient and may also be constructed of other alternative materials such as biocompatible polymers. The barriers of this embodiment may extend to form the two protuberances. This barrier may also preferably be flexible and resilient.

As a result of both the barrier and the C-shaped core 10 being preferably flexible and resilient, the protuberances are generally flexible and resilient which may allow the patient, doctor or other user to bend or distort the shape of the protuberances which may facilitate the joining of a coupling device around the outer surface of the patient's skin which will allow transmission of an electric signal in a similar fashion as wire 3 in the above described embodiment.

This coupling device, with regard to the embodiment of figure 2, may be in the form of ring 12 of electrically conductive material and/or wire. This ring 12 may be constructed of wire, iron or a similar conductive material. The ring 12 may be preferable connected to a DC rectifier which may rectify or translate data information and a power supply into an electrical signal that is transmittable and receivable across the above described magnetic coupling device.

When in use, the embodiment shown in figure 2 may receive an electrical signal via the ring 12. The signal may include data information as to controlling and regulating a medical device for which the TPDTS 42 is to be connected to and/or a power supply for said medical device and/or general data relating to the health of patient and/or other miscellaneous data.

When an electric signal is induced in the ring 12, which may be positioned around one or both of protuberances, an electro-magnetic coupling is formed between ring 12 and core 10 which induces an electro-magnetic force (EMF) in coil 9, which is wrapped around the core 10 in this embodiment. The electrical signal is fed from coil 9 to the wire 8 and this signal maybe used to regulate an active implantable medical device, supply power to an active implantable medical device or provide amendments to instructions of a preferred internal controller for the medical device.

Please note that information, data power and/or other electrical signals may also be transmitted internally from the patient and received externally by ring 12 by way of an electrical signal. This electrical signal may also be fed to an external battery and/or external controller.

The embodiment featured in figure 2, has several benefits over a rigid core design in that it is generally more biocompatible with the patient, easier for the patient to adjust to and may be less likely to cause injury to the patient if the ring 12 is accidentally detached from the arrangement shown in figure 2.

With regard to the embodiment shown in figure 2, the core is shown in a general C-shape configuration which forms an incomplete loop and as a result gap 13 is formed. This gap 13 therefore may incorporate an air gap. It is generally acknowledged that any air gap within a magnetically coupling device may substantially limit the effectiveness of any such TPDTS as it may generally increase the level of magnetic flux leakage. However, the magnetic flux leakage may be substantially lower than comparable transcutaneous energy transmission systems. Preferably, this embodiment may also include a latching means to temporarily join the two outer free ends of the protuberances and this may minimise the distance of gap

13. If the join is temporary the user may still gain the advantage that the ring 12 may be easily positioned.

The temporary joining of the free ends may be accomplished by a latching means. This latching means may preferably be magnetic with the insertion of small positioning magnets at opposed ends of the protuberances. However alternate forms of latching means are available and these include but are not limited to: a small mechanical clip or a sticky re-useable glue.

As per earlier embodiments, the embodiment of figure 2 may include a core 10 which is encased to assist in biocompatibility and/or coil 9 may shrouded or shielded from the patient's body by a shield or encasement of some form common to the art.

Preferably the core 10 may be circular in arrangement however other shapes and configurations may still achieve the same or similar net result of electro-magnetic coupling. The shape of the overall core may be configured so as to allow the return flow of magnetic flux around the core and may thereby form a flux loop. This flux loop may overcome small air gaps in the core.

Please note that the preferred embodiment shown in figure 2 also shows a gap 14 which preferably allows the connection or attachment of the ring device 12.

A further preferred embodiment of the present invention is shown in figure 3. This embodiment 46 shows a first portion 26 which is of a generally squared C-shaped configuration. This first portion 26 is embedded within the skin layer 17 of a patient. A second portion is embedded within a female socket arrangement 21. The combined effect of the first and second portions is to facilitate the combined effect of an overall core with a magnetic flux loop. In figure 3, the first portion 26 cooperates with the second portion 25 to achieve a similar effect as to the core 2 shown in figure 1.

Preferably, portion 26 is embedded beneath the skin layer 17. The ends of this portion 26 are covered by a barrier. Preferably this barrier may the patient's skin manipulated around to fit the configuration shown in figure 3. The result of the implanting of the portion 26 beneath the skin layer 17 is to have the patient skin sealed from the outside environment and thereby avoid the probability of infection. Additionally, the portion 26 in cooperation with the barrier forms two protuberances 27 which extend away from the surface of the patient's skin.

Preferably, these protuberances in this embodiment may form a male type connection designed to mate with a corresponding female connector located on the surface of socket 21.

Embedded within the socket arrangement 21 is a second portion 25 which is positioned between the outer most ends of portion 26. Around portion 25 is a coil 24. This coil 24 is preferably connected to an external rectifier, controller and/or power supply by wires 23.

Preferably, portion 25 is positioned so as to cooperate with magnetic portion 26 to form a magnetic core which is capable of forming a magnetic flux loop, in use.

Generally, an electrical signal is supplied to coil 24 by wires 23. The electrical signal in coil 24 induces an electromagnetic force in portion 25 which in turn feeds onto an electromagnetic force being generated in portion 26. Coil 15 is thereby energised by the electromagnetic flow in portion 26 and supplies the resulting electrical signal to other internal devices by way of wires 15.

The socket 21 shown in figure 3, demonstrates one of the preferred ways of mounting an embodiment of the present invention. Additionally, any socket arrangement may include a means of securing the socket 21 to the outer surface of the skin layer 17. In this embodiment, positioning magnets 18, 20, 44, & 45 may be used

to secure the socket in place. Permanent magnets 18 & 44 are preferably implanted in the skin layer of a patient and permanent magnets 20 & 45 are embedded in the socket arrangement 21. This magnetic securing means allows the socket to be easily removed and replaced by a user or patient when it is desirable to do so.

Alternately, the male and female sides of this embodiment may be reversed. For example, the protuberances 27 may extend from the socket into the indentations made in the skin layer.

Preferably, this embodiment transmits and receives data and power bi-directionally from inside the patient's body to the outside environment and also from the outside environment into the patient's body and may operate at full duplex or half duplex. This embodiment may also include wires 23, which may be encased and may extend away from the socket arrangement 21, in a cover 22.

Figure 4 shows a diagrammatical representation of a preferred embodiment of the present invention wherein the embodiment is in situ. In this figure, a cross section of a patient is shown. The external environment 39 is separated from the internal body 82 of the patient by the patient's skin barrier 81.

In this embodiment, positioned proximal to the skin barrier 81 on the inside 82 of the patient is an inner transceiver 33. This inner transceiver 33 cooperates with an outer transceiver 39 positioned outside 39 of the patient's body but proximal to the skin layer 81 transmit and receive an electrical signal between them. The inner transceiver 33 and outer transceiver 36 are preferably magnetically coupled and may exchange power and data.

The inner transceiver 33 additionally cooperates with a controller 32, which is preferably implanted in the patient's body 82. In this embodiment, the internal controller 32 receives and transmits data and power to a further medical device 30,

which is preferably a blood pump. Preferably the internal controller 32 includes a DC rectifier device, which may rectify the electrical signal received by the inner transceiver 33. Additionally this DC rectifier device may function to encode or decode an electric signal and send it to the inner transceiver for transmission to the external environment 39.

The inner controller 32 may also send and receive power to internal backup battery 31. This internal battery 31 is preferably rechargeable and is implantable and is a relatively small battery able to supply approximately 3-4V. This battery may be charged by power supplied by the inner controller 32 which is in turn received from the inner receiver 33. When the outer transceiver is not cooperating with the inner transceiver 33 or power is not being supplied by the components of the embodiment in the outside environment 39, the inner battery 31 returns the stored power to the controller 32. This will allow the medical device 30 to function even when an external power source is disconnected.

The inner controller 32 in figure 4 is shown to be controlling and supplying power to a medical device 30, which is preferably an implantable blood pump. This implantable blood pump 30 may be connected to a patient's circulatory system in either parallel or series configuration depending on the desired function of the blood pump. In this embodiment, blood is received by inlet 29 pumped by the blood pump 30 to the outlet 28. Both the inlet 29 and outlet 28 may be preferably connected to the patient's circulatory system by stenting.

The internal battery 31 or external battery 40 may also send or receive power directly to the transceiver depending on the particular configuration of the embodiment. Alternately, the inner battery may be directly connected to the medical device 30.

Preferably, the outer transceiver 36 cooperates with an external controller 35. An electrical signal is transmitted and received by the outer transceiver 36 to and from the external controller 35. The external controller 35 may be preferably carried by the patient and may be mounted external to the patient's body. This external controller 35 may be connected to a personal computer 37 for monitoring and/or adjustment by software running on the computer 37. Preferably this computer may be connected to the Internet or any computer network to submit and receive data regarding the implantable medical device and patient's status. Preferably a permanent external power supply 38 may be connected to the controller 35 which in turn may charge the external battery 40. When the permanent external power supply 38 is removed from the system, the external battery 40 may return power to the external controller 35 and then to the outer transceiver 36, which transmitting to the medical device 30 by way of the internal components.

Preferably, the external controller 35 includes a DC rectifier which is capable of converting an electrical signal into a form that can be transmitted by the outer transceiver 36 and may lead to transmission to inner transceiver 33.

Preferably the external battery 40 may a single battery or a set of batteries and also it is preferred that the battery or batteries be Nickel Metal Hydride battery capable of supplying 12V at 3800mA/Hr. This also preferred battery weighs 600g or less. This external battery 40 may be removed and replaced for purposes of additionally recharging or substitution in cases of battery failure.

Figure 5 shows a preferred method of implanting the device within the skin layer 72 of a patient. In figure 5, a portion of a patient's skin layer is shown 72 as viewed by a surgeon. Preferably, an incision 73 is made through the skin layer 72. The preferred core of one of the abovedescribed embodiments is inserted into the

incision 73. The core is positioned so that approximately half of the core protrudes out of the incision 73 and the other half is within the body of the patient. The incision is then preferably closed by stitching which fixes the core in place. The incision 73 may be of a length appropriate to the fit the approximately same length of core within it.

Figure 6 shows an alternate version of implantation of the preferred electrically conductive core of one of the abovedescribed embodiments. Several incisions may be made in the skin layer 74. These include two parallel vertical incisions 75 & 76 and two sets of further incisions 77 & 78 which extend angularly away from incisions 75 and 76 towards the centre line. Neither of these acts of incision met in the middle rather they leave a small gap between them. The result of these incisions is to form two flaps of skin 80 joined by a middle piece 79. The core may be inserted under 79 in a similar way as that described in figure 5 then the flaps 80 may be folded under the inner surface of the core and stitched in place around the core. The outer edges of the incisions 75 and 76 may be stitched together. The net result of this configuration is seal the core below the skin layer similar to the manner shown in the cross section view of figure 1.

The preferred site for implantation for any of the embodiments may be a site on the abdomen of a patient.

It may also be preferable to connect any one of the abovedescribed embodiments or various other versions of the present invention to a blood pump shown in figure 7.

The blood pump shown in figure 7 is a centrifugal pump 50 intended for implantation into a human body. The pump housing 62 may be fabricated in two parts, a front part 61 in the form of a housing body and a back part 59 in the form of a housing cover, with a smooth join therebetween, for example at 60 in Figure 7. The

pump 50 has an axial inlet 70 and a tangential outlet. The rotating part or impeller 56 is of simple form, comprising only blades 47 and a blade support 49 to hold those blades fixed relative to each other. The blades may be curved or straight, in which case they can be either radial or tilted, i.e., at an angle. This rotating part 56 will hereafter be called the impeller 56, but it also serves as a bearing component and as the rotor of a motor configuration as to be further described below whereby a torque is applied by an electromagnetic means to the impeller 37. Note that the impeller may have no shaft and that fluid enters the region of its axis 51. Some of the fluid passes in front of the support cone 49 and some behind it, so that the pump 50 can be considered of two-sided open type, as compared to conventional open centrifugal pumps, which are only open on the front side. Approximate dimensions found adequate for the pump 50 to perform as a ventricular assist device, when operating at speeds 2000 - 4000 rpm, are outer blade diameter of 40 mm, outer housing average diameter 60mm, and housing axial length 40mm.

As the blades 47 move within the housing, some of the fluid passes through the gaps, much exaggerated in Figure 7, between the blade edges and the housing front face 48 and the housing back face 57. In all open centrifugal pumps, the gaps are made small because this leakage flow lowers the pump hydrodynamic efficiency. In the pump disclosed in this embodiment, the gaps are made slightly smaller than is conventional in order that the leakage flow can be utilised to create a hydrodynamic bearing. For the hydrodynamic forces to be sufficient, the blades may be tapered, so that the gap is larger at the leading edge of the blades than at the trailing edge. The blood which passes through the gap thus experiences a wedge shaped restriction which generates a thrust, as described in Reynolds' Theory of Lubrication. The thrust is proportional to the square of the blade thickness of the edge, and thus thick blades

are favoured, since if the proportion of the pump cavity filled by blades is constant, then the net thrust force will be inversely proportional to the number of blades. However, the blade edges can be made to extend as tails from thin blades in order to increase the blade area adjacent to the walls.

In one particular form, the tail join adjacent blades so as to form a complete shroud with wedges or tapers incorporated therein. An example of a shroud design as well as other variations on the blade structure will be described later in this specification.

For manufacturing simplicity, the housing front face 48 can be conical, with an angle of around 45^0 so that it provides both axial and radial hydrodynamic forces. Other angles are suitable that achieve the functional requirements of this pump including the requirements for both axial and radial hydrodynamic forces.

Other curved surfaces are possible provided both axial and radial hydrodynamic forces can be produced as a result of rotation of the blades relative to the housing surfaces.

In this preferred embodiment, for manufacturing simplicity and for uniformity in the flow axial direction RR, the housing back face 57 is made flat over the bearing surfaces, i.e. under the blade edges. With this the case, a slacker tolerance on the alignment between the axes of the front part 61 and back part 59 of the housing 62 is permissible. An alternative is to make the back face 57 conical at the bearing surfaces with taper in the opposite direction to the front face 48, so that the hydrodynamic forces from the back face will also have radial components. Tighter tolerance on the axes alignment would then be required, and some of the flow would have to undergo a reversal in its axial direction. There may be some advantage in making the housing

surfaces and blade edges non-straight, with varying tangent angle, although this will impose greater manufacturing complexity.

There are several options for the shape of the taper, but in the preferred embodiment the amount of material removed simply varies linearly or approximately linearly across the blade. For the back face, the resulting blade edges are then planes at a slight inclination to the back face. For the front face, the initial blade edges are curved and the taper only removes a relatively small amount of material so they still appear curved. Alternative taper shapes can include a step in the blade edge, though the corner in that step would represent a stagnation line posing a thrombosis risk.

For a given minimum gap, at the trailing blade edge, the hydrodynamic force is maximal if the gap at the leading edge is approximately double that at the trailing edge. Thus the taper, which equals the leading edge gap minus the trailing edge gap, should be chosen to match a nominal minimum gap, once the impeller has shifted towards that edge. Dimensions which have been found to give adequate thrust forces are a taper of around 0.05 mm for a nominal minimum gap of around 0.05 mm, and an average circumferential blade edge thickness of around 5 mm for 4 blades. For the front face, the taper is measured within the plane perpendicular to the axis. The axial length of the housing between the front and back faces at any position should then be made about 0.2 mm greater than the axial length of the blade, when it is coaxial with the housing, so that the minimum gaps are both about 0.1 mm axially when the impeller 56 is centrally positioned within the housing 62. Then, for example, if the impeller shifts axially by 0.05 mm, the minimum gaps will be 0.05mm at one face and 0.15 mm at the other face. The thrust increases with decreasing gap and would be much larger from the 0.05 mm gap than from the 0.15 mm gap, about 14 times larger

for the above dimensions. Thus there is a net restoring force away from the smaller gap.

Similarly, for radial shifts of the impeller the radial component of the thrust from the smaller gap on the conical housing front face would offer the required restoring radial force. The axial component of that force and its torque on the impeller would have to be balanced by an axial force and torque from the housing back face, and so the impeller will also have to shift axially and tilt its axis to be no longer parallel with the housing axis. Thus as the person moves and the pump is accelerated by external forces, the impeller will continually shift its position and alignment, varying the gaps in such a way that the total force and torque on the impeller 56 match that demanded by inertia. The gaps are so small, however that the variation in hydrodynamic efficiency will be small, and the pumping action of the blades will be approximately the same as when the impeller is centrally located.

While smaller gaps imply greater hydrodynamic efficiency and greater bearing thrust forces, smaller gaps also demand tighter manufacturing tolerances, increase frictional drag on the impeller, and impose greater shear stress an the fluid. Taking these points in turn, for the above 0.05 mm tapers and gaps, tolerances of around ±0.015 mm are needed which imposes some cost penalty but is achievable. A tighter tolerance is difficult, especially if the housing is made of a plastic; given the changes in dimension caused by temperature and possible absorption of fluid by plastic. The frictional drag for the above gaps produces much smaller torque than the typical motor torque. Finally, to estimate the shear stress, consider a rotation speed of 3000 rpm and a typical radius of 15 mm, at which the blade speed is 4.7 ms^{-1} and the average velocity shear for an average gap of 0.075 mm is $6.2x10^{4}s^{-1}$. For blood of dynamic viscosity $3.5x10^{-3}$ $kgm^{-1}s^{-1}$, the average shear stress would be 220 Nm^{-2}.

Other prototype centrifugal blood pumps with closed blades have found that slightly larger gaps, e.g. 0.15 mm, are acceptable for haemolysis. A major advantage of the open blades of the present invention is that a fluid element that does pass through a blade edge gap will have a very short residence time in that gap, around $2x10^{-3}$ s. and the fluid element will most likely be swept through the pump without passing another blade edge.

To minimise the net force required of the hydrodynamic bearings, the net axial and radial hydrodynamic forces on the impeller from the bulk fluid flow should be minimised, where "bulk" here means other than from the bearing thrust surfaces.

One method of minimising the bulk radial hydrodynamic force is to use straight radial blades with virtually no radial component. The radial force on the impeller depends critically on the shape of the output flow collector or volute 35. The shape should be designed to minimise the radial impeller force over the desired range of pump speeds without excessively lowering the pump efficiency. The optimal shape will have a roughly helical perimeter between the "cut water" and outlet. The radial force can also be reduced by the introduction of an internal division in the volute 35 to create a second output flow collector passage, with tongue approximately diametrically opposite to the tongue of the first passage.

In regard to the bulk axial hydrodynamic axial force, if the blade cross-section is made uniform in the axial direction along the relational axis, apart from the conical front edge, then the pressure acting on the blade surface (excluding the bearing edges) will have no axial component. This also simplifies the blade manufacture. The blade support cone 49 must then be shaped to minimise disturbance to the flow over the range of speed, while maintaining sufficient strength to prevent relative blade movement. The key design parameter affecting the axial force is the angle of the cone.

The cone is drawn in figure 3 as having the same internal diameter as the blades, which may aid manufacture. However, the cone could be made with larger or smaller internal diameter to the blades. There may be an advantage in using a non-axisymmetric support "cone", e.g. with a larger radius on the trailing surface of a blade than the radius at the leading surface of the next blade. If the blades are made with non-uniform cross-section to increase hydrodynamic efficiency, then any bulk hydrodynamic axial force on them can be balanced by shaping the support cone to produce an opposite bulk hydrodynamic axial force on it.

Careful design of the entire pump, employing computational fluid dynamics, is necessary to determine the optimal shapes of the blades 47, the volute 58, the support cone 49 and the housing 62, in order to maximise hydrodynamic efficiency while keeping the bulk fluid hydrodynamic forces, shear and residence times low. All edges and the joins between the blades and the support cone should be smoothed.

The means of providing the driving torque on the impeller 56 of the preferred embodiment of the invention is to encapsulate permanent magnets in the blades 30 of the impeller 56 and to drive them with a rotating magnetic field pattern from oscillating currents in the windings 53 and 54, fixed relative to the housing 62. Magnets of high remanence such as sintered rare-earth magnets should be used to maximise motor efficiency. The magnets should be aligned axially or approximately axially, with alternating polarity for adjacent blades. Thus there must be an even number of blades. Since low blade number is preferred for the bearing force, and since two blades would not have sufficient bearing stiffness for rotation about an axis through the blades and perpendicular to the pump housing (unless the blades are very curved), four blades are recommended. A higher number of blades, for example 6 or 8 blades, may also allow the pump to function.

There are many options for locating the magnets within the blades 47. The most preferred is for the blade to be made of magnet material apart from a biocompatible shell or coating to prevent fluid corroding magnets and to prevent magnet material (which may be toxic) entering the blood stream. The coatings should be sufficiently durable especially at blade corners to withstand rubbing during start-up or during inadvertent bearing touch down.

Finally, to create the alternating blade polarity the impeller must be placed in a special pulse magnetisation fixture, with an individual coil surrounding each blade. The support cone may acquire some magnetism near the blades, with negligible influence.

All edges in the pump should be radiused and surfaces smoothed to avoid possible damage to formed elements of the blood.

The windings 53 and 54 of the preferred embodiment are slotless or air-gap windings, following the blade curvature, with the same pole number as the impeller, namely four poles in the preferred embodiment. A ferromagnetic iron yoke 52 of conical form for the front winding and an iron ferromagnetic yoke 55 of annular form for the back winding may be placed on the outside of the windings to increase the magnetic flux densities and hence increase motor efficiency. The winding thicknesses should be designed for maximum motor efficiency, with the sum of their actual thicknesses somewhat less than but comparable to the magnet axial length. The yokes can be made of solid ferromagnetic material such as iron. To reduce "iron" losses, the yokes 41 can be laminated, for example by helically windings thin strip, or can be made of iron/powder epoxy composite. Alternatively they can be helically wound to reduce iron losses. The yokes should be positioned such that there is zero net axial magnetic force on the impeller when it is positioned such that there is zero net axial

magnetic force on the impeller when it is positioned centrally in the housing. The magnetic force is unstable and increases linearly with axial displacement of the impeller away from the central position, with the gradient being called the positive stiffness of the magnetic force. This unstable magnetic force must be countered by the hydrodynamic bearings, and so the stiffness should be made as small as possible. Choosing the yoke thickness such that the flux density is at the saturation level reduces the stiffness and gives minimum mass. An alternative would be to have no iron yokes, completely eliminating the unstable axial magnetic force, but the efficiency of such designs would be lower and the magnetic flux density in the immediate vicinity of the pump may violate safety standards and produce some tissue heating. In any case, the stiffness is acceptably small for slotless windings with the yokes present. Another alternative would be to insert the windings in slots in laminated iron stators which would increase motor efficiency and enable use of less magnet material and potentially lighter impeller blades. However the unstable magnetic forces would be significant for such slotted motors. Also, the necessity for fat blades to generate the required bearing forces allows room for large magnets, and so slotless windings are chosen in the preferred embodiment.

The winding connection of the preferred embodiment is for three wires, one wire per phase, to connect a sensorless electronic controller to winding 53.

Alternatively, the windings and yokes may be encapsulated within the housing during fabrication. In this way, the separation between the winding and the magnets is minimised increasing the motor efficiency and the housing is thick, increasing its mechanical stiffness. Alternatively, the windings can be positioned outside the housing and the thickness of these windings is preferably at least 2 mm for sufficient stiffness.

The combining of the motor and bearing components into the impeller in the preferred embodiment provides several key advantages. The rotor consequently has very simple form, with the only cost of the bearing being tight manufacturing tolerances. The rotor mass is very low, minimising the bearing force needed to overcome weight. Also with the bearings and the motor in the same region of the rotor, the bearings forces are smaller than if they had to provide a torque to support magnets at an extremity of the rotor.

A disadvantage of the combination of functions in the impeller is that its design is a coupled problem. The optimisation should ideally link the fluid dynamics, magnetics and bearing thrust calculations. In reality, the blade thickness can first roughly sized to give adequate motor efficiency and sufficient bearing forces with a safety margin. Fortuitously, both requirements are met for four blades of approximate average circumferential thickness 5 mm. The housing, blade and support cone shapes can then be designed using computational fluid dynamics, maintaining the above minimum average blade thickness. Finally the motor stator, i.e. winding and yoke, can be optimised for maximise motor efficiency

Figure 8 shows a preferred impeller of an embodiment of the pumping device. In this embodiment, the impeller 63 of a pump features four blades 65. Please note that any number of blades greater than 2 may be chosen. These blades 65 may have a distinct shape. In this case of this preferred embodiment, the distinct shape of each blade is generally tear-shaped. Each blade in this embodiment may be joined together with a bridging portion 66. Preferably this bridging portion has a streamlined shaped to allow minimal damage to the pumping fluid.

In figure 9, a further preferred embodiment of an impeller 67 is shown. In this preferred embodiment each one of the blades 69 is generally shark-fin shaped. It is

important to note that the blades 69 of the impellers 63 & 67 are both preferably incorporate a hydrodynamic bearing in the form of a taper across the outer surfaces of the blades.

The impeller 67 preferably has four blades 69 which are joined by bridging portions 70. The bridging portions are generally streamlined and preferably, in this embodiment, do not generally provide a hydrodynamic force. In alternate designs of the impellers these bridging portions may be fashioned so as to provide lift or hydrodynamic thrust force.

Another preferred feature of impellers 67 & 63 is a relatively small flat sections 64 & 68. These sections 64 & 68 may act as a reference point for measurements and activities to be use by external testing equipment and/or manufacturing equipment.

Another preferred embodiment is depicted in figure 10. This figure shows a blood pump 77 implanted within the body of a patient 86. In this embodiment, the blood pump 77 is connected to the heart 85 of the patient 86 through an apex of the left ventricle 83 by way of an inflow cannula 82. In use, the pump 77 pumps from the heart 85 to the ascending aorta 75. Fluid communication between the ascending aorta and an outlet of the pump 77 is achieved by use of an outflow cannula 84. The outflow cannula 84 is preferably constructed of velour and covered or protected by a bend relief preferably made of polypropylene. The inflow cannula is preferably constructed of silicone rubber. When implanted the pump 77 is preferably mounted under a left lung 76 of the patient.

Preferably, the pump communicates data, and receives pumping speed instructions and power from a pump controller 79. Preferably the communication of data and power is achieved by use of a TPDTS (not shown in figure 10). The

controller 79 receives power from a first battery 78 and, in the event of a first battery failure, a second battery 81 is capable of powering the entire system. Additionally, power may be supplied directly to the controller 79 from a household mains power supply (not shown in figure 10). Preferably, the controller 79 and batteries 78 & 81 may be mounted on a belt 80, which may be worn by the patient 86. It may also be preferred that the batteries 78 & 81 and the controller 79 may be balanced on the belt to promote comfort for the patient 86. Also, the belt 80 may also include the controller 79 and batteries 78 & 81 as a single unit (not shown in figure 10).

In another preferred embodiment of the present invention, as shown in figure 11, a conductive ring 89 is implanted within a patient's skin layer 88. Wrapped around at least a portion of the implanted ring 89 is a electrically conductive coil 90. Preferably a hole 87 is made in skin layer so that it passes under the outer most edge of the ring 89. This hole 87 allows for the attachment of a piece of wire (not shown). This wire, in use, passes through the hole 87 and allows for communication of a data signal and/or power to and from coil 90. When an electrical signal is passed through the wire, the signal generates an EMF in ring 89 and this EMF passes to coil 90 and generates a complementary signal in the wire of coil 90.

Preferably, the placement of the ring 89 may be a staged procedure which may place the ring 89 and then, after the insertion wound has healed and the ring is mechanically stable, a tunnel or hole 87 may be formed for an external power wire which preferably does not actually make contact with the ring 89. The hole 87 may be formed by punching out a circular tunnel using a customised tool or circular cutter. The hole 87 may be relatively small.

Another embodiment of a procedure of implantation may involve a procedure as illustrated by figures 12 and 13. Figure 12 shows a relatively flat flap of skin 92

protruding from the surface of the patient's ordinary skin layer 93. Inside the flap 92 is embedded a conductive ring 94 and passing through the approximate center of the flap 92 is a hole 127. A wire 91 is preferably passed through hole 127. Preferably, a coil (not shown in figure 12 or 13) is attached around the ring 94. This coil in implanted within the body of the patient. In use, the coil and the wire 91 communicate to transmit and receive data signals, instructions and/or power.

Such an implantation procedure may involve pinching up a flap of skin which is dissected from the inside to form a pocket which may enclose the ring. Alternatively, it may involve taking advantage of an existing anatomical flap (such as an earlobe of a patient) which is similarly dissected from the inside.

Preferably, this pinching may also have the benefit of making the hole or tunnel comparatively short so that re-epithelialisation of the tunnel would be facilitated.

In a further embodiment of the present invention, a staged implantation may be preferable. It may be desirable to power the system without mechanically interfering with the tunnel or hole site of the primary external wire so as not to cause mechanical trauma to the area of implantation. Thus a means of temporarily powering the system is desirable. This may be achieved by the use of a temporary wire placed through the ring in a location deeper relative to the skin layer proximal to the implantation site. This may be achieved with the temporary wire being temporarily implanted with the use of a surgical needle.

In further embodiments as depicted in figure 14, the shape of the ring 96 does not have to be circular but rather forms an RMI² flux loop. It may be desirable to include with the system or device a bent ring 96 with unequal dimensions. This may provide an anchor means in the tissue or skin layer 99 of the patient. The pedestal

arrangement may also be used for mechanical stability. In figure 14, the bent ring is implanted below the skin layer 99. This implantation forms a protuberance 97. A small hole or tunnel may be made through the protuberance 97 at a point proximal to point 101 and an external wire 98 may be passed through the hole.

A further bent ring arrangement of another embodiment is depicted in figure 15. In this configuration, a ring 102 has been deformed into a general L-shaped configuration. An internal coil 103 is wound around a portion of the ring 102. The upper end 106 of the ring 102, when implanted, may produce a protuberance 105. This protuberance 105 may be pierced with a hole and an external wire may be passed through this hole. The wire may then communicate electric signals to and from coil 103.

It may also be preferable to include a textured surface to attach to the conductive ring device. In a further embodiment depicted in figure 16, a subcutaneous textured surface 112 may be used to anchor or maintain the conductive ring 109 in the correct shape and orientation. An implanted coil 110 is wound around the ring 109. The ring extends in a protuberance 108 in the skin layer 111. A gap 128 is made in the protuberance 108 and an external wire 107 is passed through the gap 128. This wire 107 may communicate with coil 110 by transmitting and receiving electric signals along the ring 109.

A further embodiment of the present invention is depicted in figure 17. If the hole or tunnel 118 through the conductive ring 115 is relatively small, it is expected that a full epithetical covering may occur. A non metallic "sleeper" ring 116, similar to a earring, may help maintain the tunnel and stop abrasive wear from the external wire 117. In this figure, the ring 115 is depicted beneath the skin layer 114 and wrapped around the ring 115 is a coil 113.

In circumstances where damage or infection to the skin are likely, a backup ring can be implanted distant from the primary ring or alternatively, a temporary primary wire may be subcutaneously tunnelled through a deeper part of the ring using a needle. In order to have the lowest profile protuberance, a second ring may be placed through the primary wire and through this second ring.

In a further embodiment depicted in figure 18, a U-shaped tunnel 120 is implanted the skin layer of a patient 119 and also through a fully implanted ring 124. An implanted coil 123 is wrapped around the ring 124. A wire 122 may be passed through the U-shaped tunnel 120. Preferably, the wire 122 may be textured (to promote tissue incorporation) and thin, this may provide a stable biological interface which may be less subject to infection than a standard percutaneous lead.

In the case of infection or initial temporary power, a second skin entry 126 for an additional primary wire may be created to allow this second primary wire to communicate with the ring 124 and the coil 123.

The above description only describes some of the embodiments of the present inventions and modification, obvious to those skilled in the art can be made thereto without departing from the scope and spirit of the present invention.

Claims

1. A device for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient; said device including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element so as to permit the transmission of an electro-magnetic signal by transcutaneous electro-magnetic coupling between said first element, said core and said second element, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally within said patient.

2. The device of claim 1 wherein said first element can transmit or receive an electro-magnetic signal.

3. The device of claims 1 or 2 wherein said second element can transmit or receive an electro-magnetic signal.

4. The device of any one of the claims 1 to 3 wherein said electric signal including data information and/or power.

5. The device of any one of the claims 1 to 4 wherein said core including a plurality of portions.

6. The device of any one of the claims 1 to 5 wherein said transmission is from direct current to direct current.

7. The device of any one of the claims 1 to 6 wherein said first element comprises at least a length of wire.

8. The device of any one of the claims 1 to 7 wherein said second element comprises at least a length of wire.

9. The device of claims 7 or 8 wherein said wire forms a coil around at least one portion.

10. The device of claim 9 wherein said wire includes polyurethane coated copper litz wire.

11. The device of any one of the claims 1 to 10 wherein said first element in a generally ring shaped configuration.

12. The device of any one of the claims 1 to 11 wherein said second element is coiled around the core.

13. The device of any one of the claims 1 to 12 wherein said at least one portion of said core pierces the skin layer of patient.

14. The device of any one of the claims 1 to 12 wherein no portion of said core pierces the skin layer of patient

15. The device of any one of the claims 1 to 14 wherein said core forms a generally continuous loop.

16. The device of any one of the claims 1 to 15 wherein said core forms a continuous shape generally in rectangular or square configuration.

17. The device of any one of the claims 1 to 16 wherein said core generates a relatively small amount of amount magnetic flux leakage.

18. The device of any one of the claims 1 to 17 wherein said device has a transmission efficiency in the range of 70% to 90%.

19. The device of any one of the claims 1 to 18 said device is connected to at least one controller and/or rectifier.

20. The device of any one of the claims 1 to 19wherein a portion of the device external to the patient's body is encased in a socket arrangement.

21. The device of any one of the claims 1 to 20 wherein said device cooperates with a blood pump.

22. The device of claim 21 wherein said blood pump is a centrifugal type pump.

23. The device of claims 21 or 22 wherein said pump includes an impeller

24. The device of claims 21, 22 or 23 wherein said impeller is hydrodynamically suspended.

25. The device of any one of the claims 1 to 24 wherein the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

26. The device of any one of the claims 1 to 25 wherein the first element is secured in place by at least one clip.

27. The device of any one of the claims 1 to 26 wherein said device is adapted for relatively long term use.

28. The device of any one of the claims 1 to 27 wherein said long term use is of a period greater than 1 week.

29. The device of any one of the claims 1 to 28 wherein said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

30. A system for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient; said device including: a core positioned so as to cooperate with a first electrically conductive element and a

second electrically conductive element so as to permit the transmission of an electro-magnetic signal by transcutaneous electro-magnetic coupling between said first element, said core and said second element and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally within said patient.

31. The system of claim 30 wherein said first element can transmit or receive an electro-magnetic signal.

32. The system of any one of the claims 30 or 31 wherein said second element can transmit or receive an electro-magnetic signal.

33. The system of any one of the claims 30 to 32 wherein said electro-magnetic signal including data information and/or power.

34. The system of any one of the claims 30 to 33 wherein said core including a plurality of portions.

35. The system of any one of the claims 30 to 34 wherein said transmission is from direct current to direct current.

36. The system of any one of the claims 30 to 35 wherein said first element comprises at least a length of wire.

37. The system of any one of the claims 30 to 36 wherein said second element comprises at least a length of wire.

38. The system of any one of the claims 30 to 37 wherein said wire forms a coil around at least one portion.

39. The system of any one of the claims 30 to 38 wherein said wire includes polyurethane coated copper litz wire.

40. The system of any one of the claims 30 to 39 wherein said first element in a generally ring shaped configuration.

41. The system of any one of the claims 30 to 40 wherein said second element is coiled around the core.

42. The system of any one of the claims 30 to 41 wherein said at least one portion of said core pierces the skin layer of patient.

43. The system of any one of the claims 30 to 42 wherein no portion of said core pierces the skin layer of patient.

44. The system of any one of the claims 30 to 43 wherein said core forms a generally continuous loop.

45. The system of any one of the claims 30 to 44 wherein said core forms a continuous shape generally in rectangular or square configuration.

46. The system of any one of the claims 30 to 45 wherein said core generates a relatively small amount of amount magnetic flux leakage.

47. The system of any one of the claims 30 to 46 wherein the transmission efficiency of the device is in the range of 70% to 90%.

48. The system of any one of the claims 30 to 47 wherein, said device is connected to at least one controller and/or rectifier.

49. The system of any one of the claims 30 to 48 wherein a portion of the device external to the patient's body is encased in a socket arrangement.

50. The system of any one of the claims 30 to 50 wherein said device cooperates with a blood pump.

51. The system of claim 50 wherein said blood pump is a centrifugal type pump.

52. The device of claims 50 or 51 wherein said pump includes an impeller

53. The device of claims 50, 51 or 52 wherein said impeller is hydrodynamically suspended.

54. The system of any one of the claims 30 to 53 wherein the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

55. The system of any one of the claims 30 to 54 wherein the first element is secured in place by at least one clip.

56. The system of any one of the claims 30 to 55 wherein said device is adapted for relatively long term use.

57. The system of claim 56 wherein said long term use is of a period greater than 1 week.

58. The system of claims 56 or 57 wherein said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

59. A method for transmission of an electro-magnetic signal to an active implanted medical device across the skin layer of a patient including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use, is positioned

externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient.

60. The method of claim 59 wherein said first element can transmit or receive an electric signal.

61. The method of any one of the claims 59 or 60 wherein said second element can transmit or receive an electric signal.

62. The method of any one of the claims 59 to 61 wherein said electric signal including data information and/or power.

63. The method of any one of the claims 59 to 62 wherein said core including a plurality of portions.

64. The method of any one of the claims 59 to 63 wherein said transmission is from direct current to direct current.

65. The method of any one of the claims 59 to 64 wherein said first element comprises at least a length of wire.

66. The method of any one of the claims 59 to 65 wherein said second element comprises at least a length of wire.

67. The method of any one of the claims 59 to 66 wherein said wire forms a coil around at least one portion.

68. The method of any one of the claims 59 to 67 wherein said wire includes polyurethane coated copper litz wire.

69. The method of any one of the claims 59 to 68 wherein said first element in a generally ring shaped configuration.

70. The method of any one of the claims 59 to 69 wherein said second element is coiled around the core

71. The method of any one of the claims 59 to 70 wherein said at least one portion of said core pierces the skin layer of patient

72. The method of any one of the claims 59 to 71 wherein no portion of said core pierces the skin layer of patient

73. The method of any one of the claims 59 to 72 wherein said core forms a generally continuous loop.

74. The method of any one of the claims 59 to 73 wherein said core forms a continuous shape generally in rectangular or square configuration.

75. The method of any one of the claims 59 to 74 wherein said core generates a relatively small amount of amount magnetic flux leakage.

76. The method of any one of the claims 59 to 75 wherein the transmission efficiency of the device is in the range of 70% to 90%.

77. The method of any one of the claims 59 to 76 wherein, said device is connected to at least one controller and/or rectifier.

78. The method of any one of the claims 59 to 77 wherein a portion of the device external to the patient's body is encased in a socket arrangement.

79. The method of any one of the claims 59 to 78 wherein said device cooperates with a blood pump.

80. The method of claim 79 wherein said blood pump is a centrifugal type pump.

81. The method of claims 79 or 80 wherein said pump includes an impeller

82. The method of claims 79, 80 or 81 wherein said impeller is hydrodynamically suspended.

83. The method of any one of the claims 59 to 82 wherein the first element is positioned and secured in place by position magnets which cooperate with opposed positioning magnets implanted within the patient's skin layer.

84. The method of any one of the claims 59 to 83 wherein the first element is secured in place by at least one clip.

85. The method of any one of the claims 59 to 84 wherein said device is adapted for relatively long term use.

86. The method of any one of the claims 59 to 85 wherein said long term use is of a period greater than 1 week.

87. The method of any one of the claims 59 to 86 wherein said device is implanted in skin layer near, adjacent, about or proximal to a site on the abdomen of a patient.

88. The device of any one of claims 1 to 29 wherein said core forms a flux loop and said core is formed of at least one magnetic portion.

89. The device of any one of claims 1 to 88 wherein said skin layer is a closed skin layer.

90. The method of any one of claims 59 to 87 wherein said core forms a flux loop and said core is formed of at least one magnetic portion.

91. The method of any one of claims 59 to 87 wherein said skin layer is a closed skin layer.

92. A method for implanting a device; wherein said device is capable transmission of an electro-magnetic signal to an active implanted medical device across the skin layer of a patient and comprises a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient; and wherein said method includes:

i) making a incision in a skin layer of a patient;

ii) inserting said core partially into said incision; and

iii) closing said incision;

93. The method of claim 92 wherein said incision is closed by stitching.

94. A method for implanting a device; wherein said device is capable of transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient and comprises a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by electro-magnetic coupling, when in use, and wherein said first electrically conductive element, when in use is positioned externally to said patient; and said second electrically conductive element, when in use, is positioned internally to said patient; and wherein said method includes:

i) making a series of incisions in a skin layer of said patient;

ii) inserting said core partially into said incision

iii) covering and sealing said core with a skin layer; and

iv) closing and sealing said incision.

95. The method of claim 94 wherein closing and sealing is achieved by stitching.

96. A device for transmission of an electro-magnetic signal to an active implanted medical device across a skin layer of a patient including: a core positioned so as to cooperate with a first electrically conductive element and a second electrically conductive element to facilitate the transmission of an electro-magnetic signal by transcutaneous electo-magnetic coupling, in use, and wherein said first electrically conductive element, when in use, is positioned externally to said patient; and second electrically conductive element, when in use, is positioned internally to said patient and wherein said device includes a series of interlocking rings.

97. A device as described with reference to any one of figures 1 to 18.

98. The system of claims 56 or 57 wherein said device is implanted in skin layer near, adjacent, about or proximal to a site on the earlobe of a patient.

99. The method of any one of the claims 59 to 86 wherein said device is implanted in skin layer near, adjacent, about or proximal to a site on the earlobe of a patient.

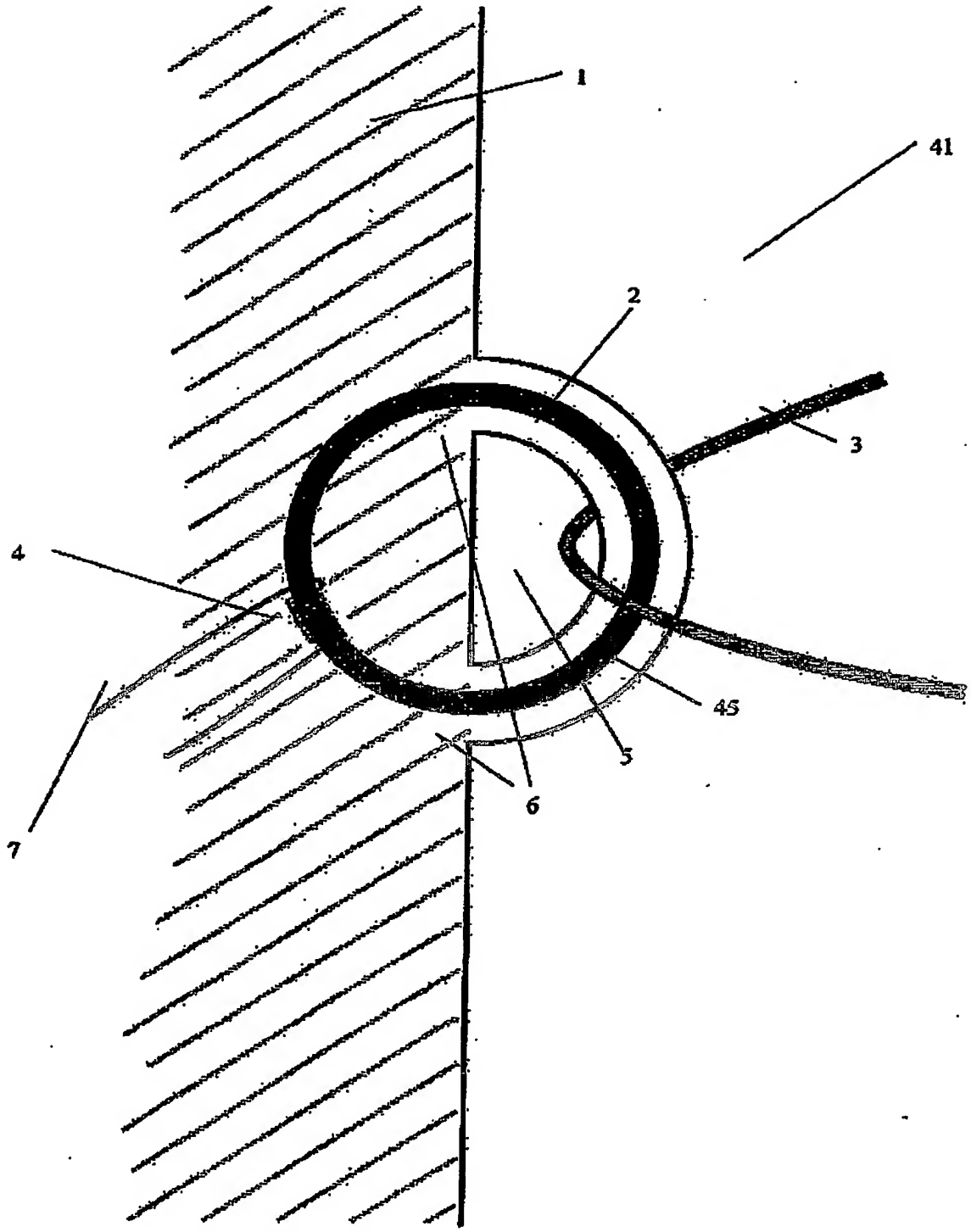


Figure 1

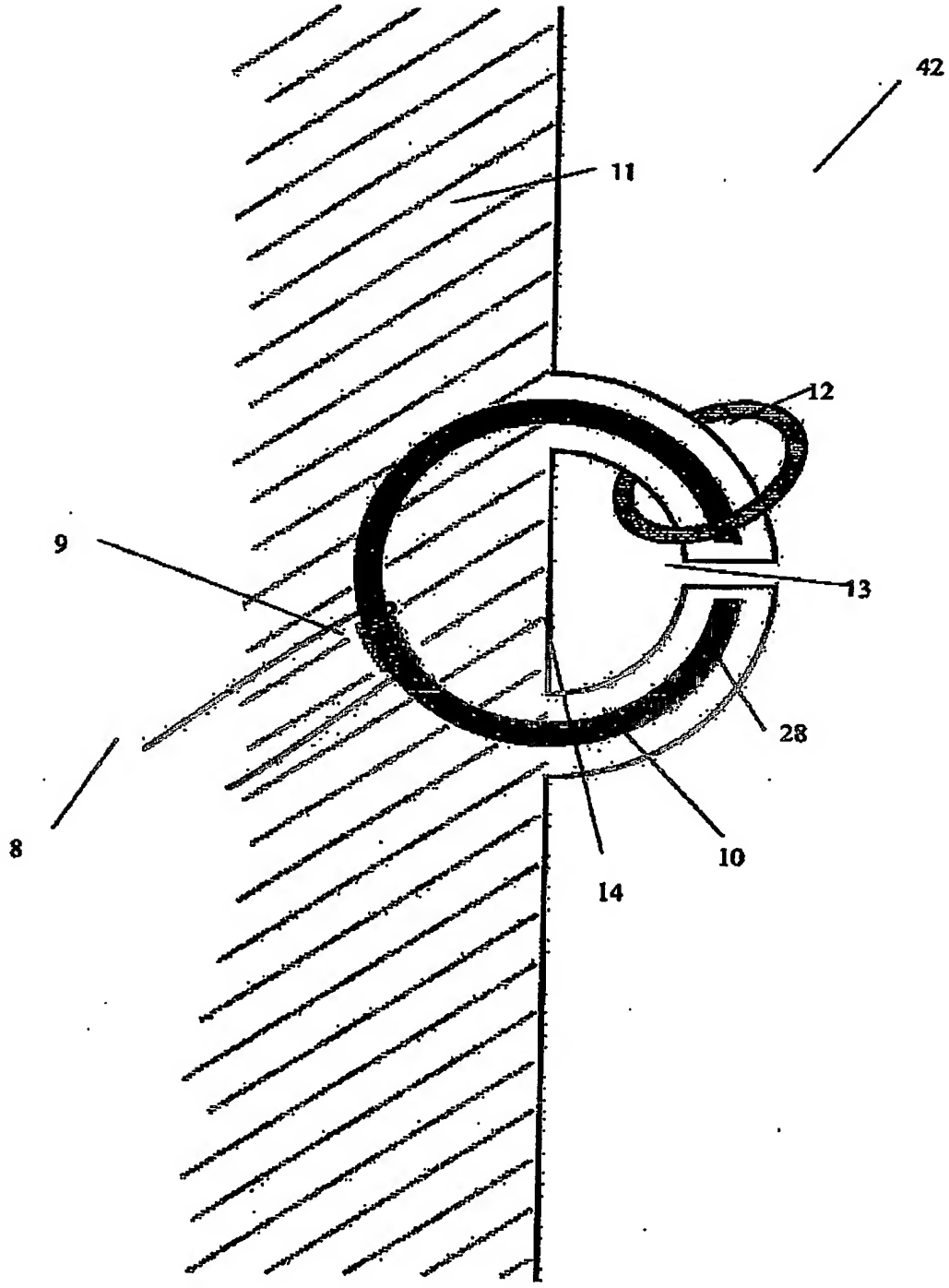
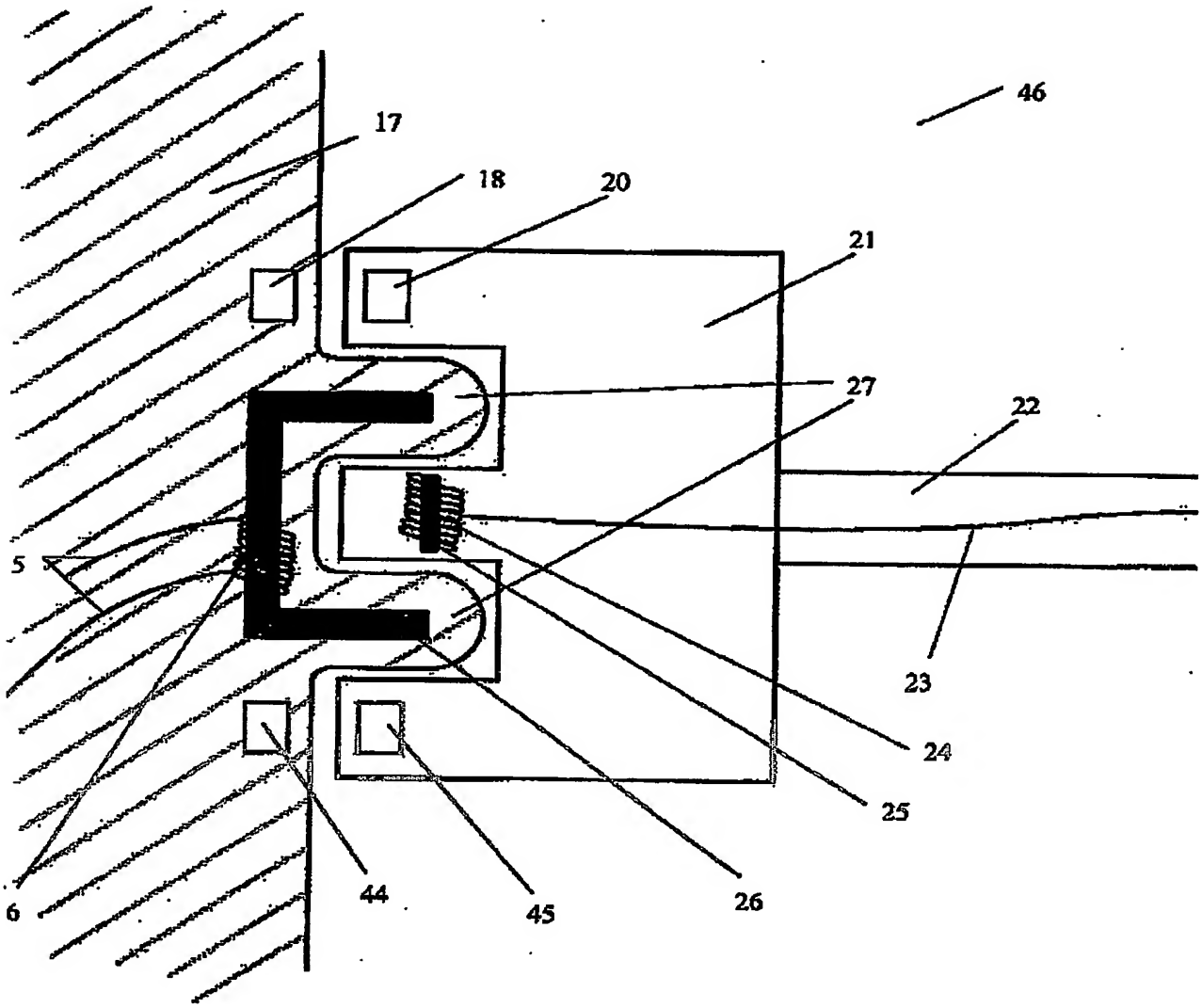


Figure 2



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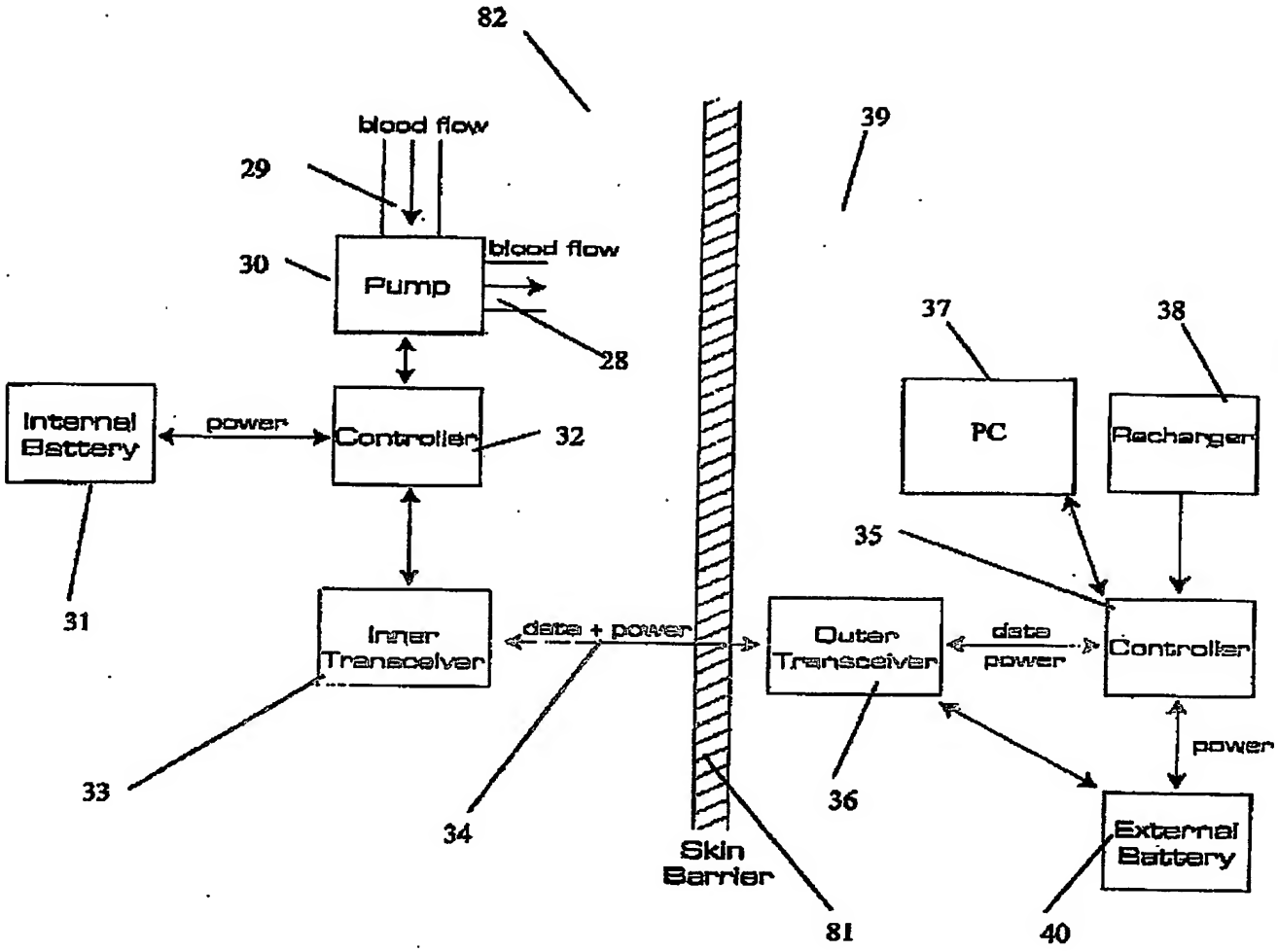

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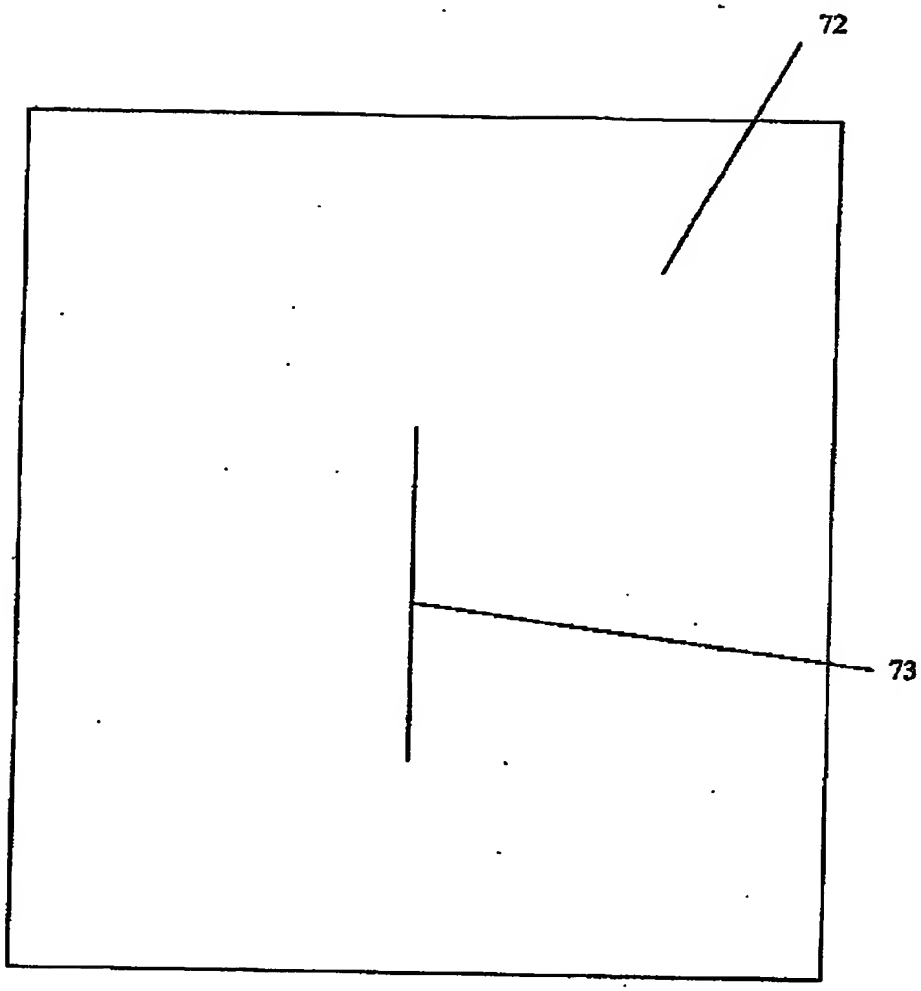

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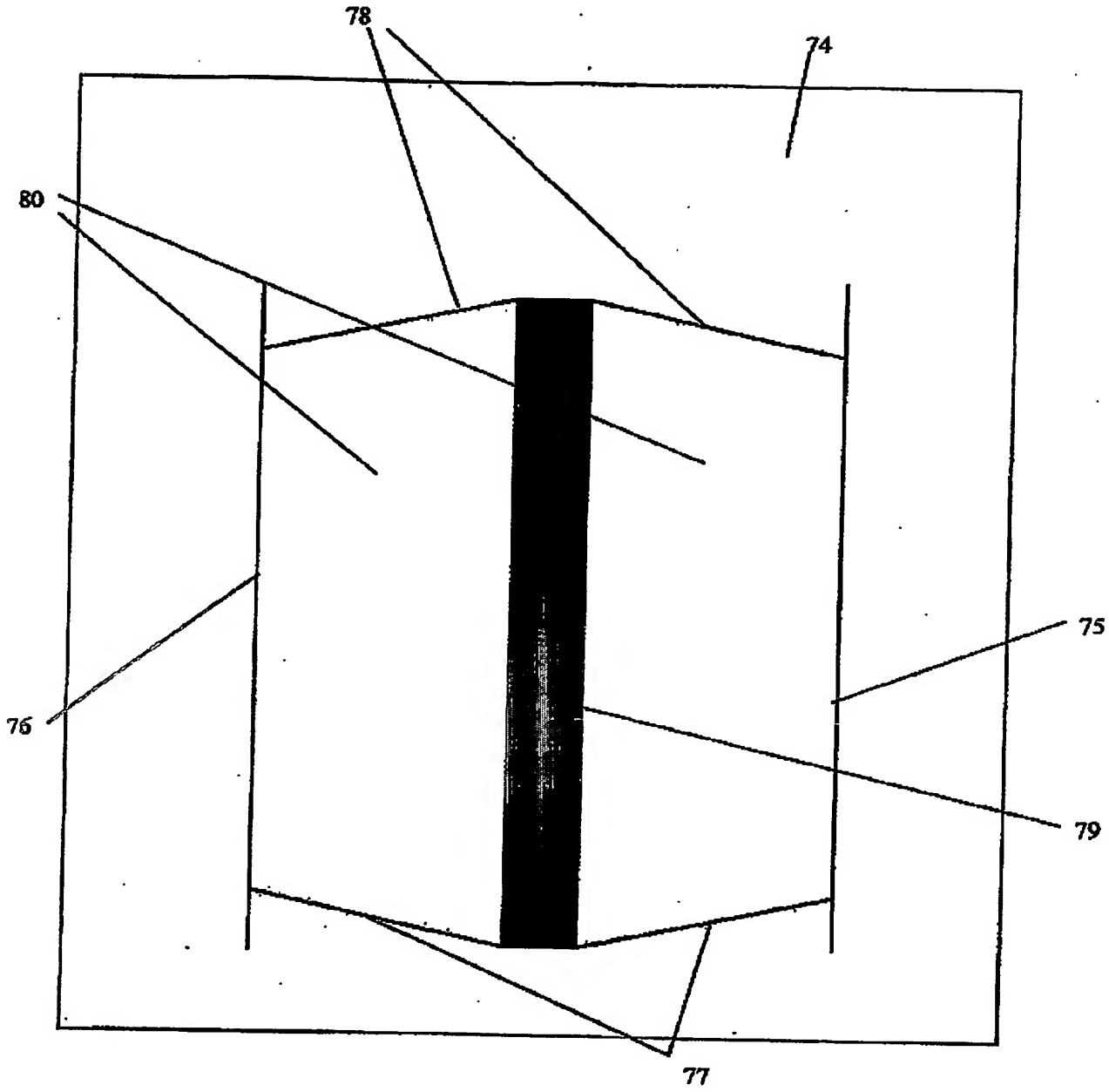

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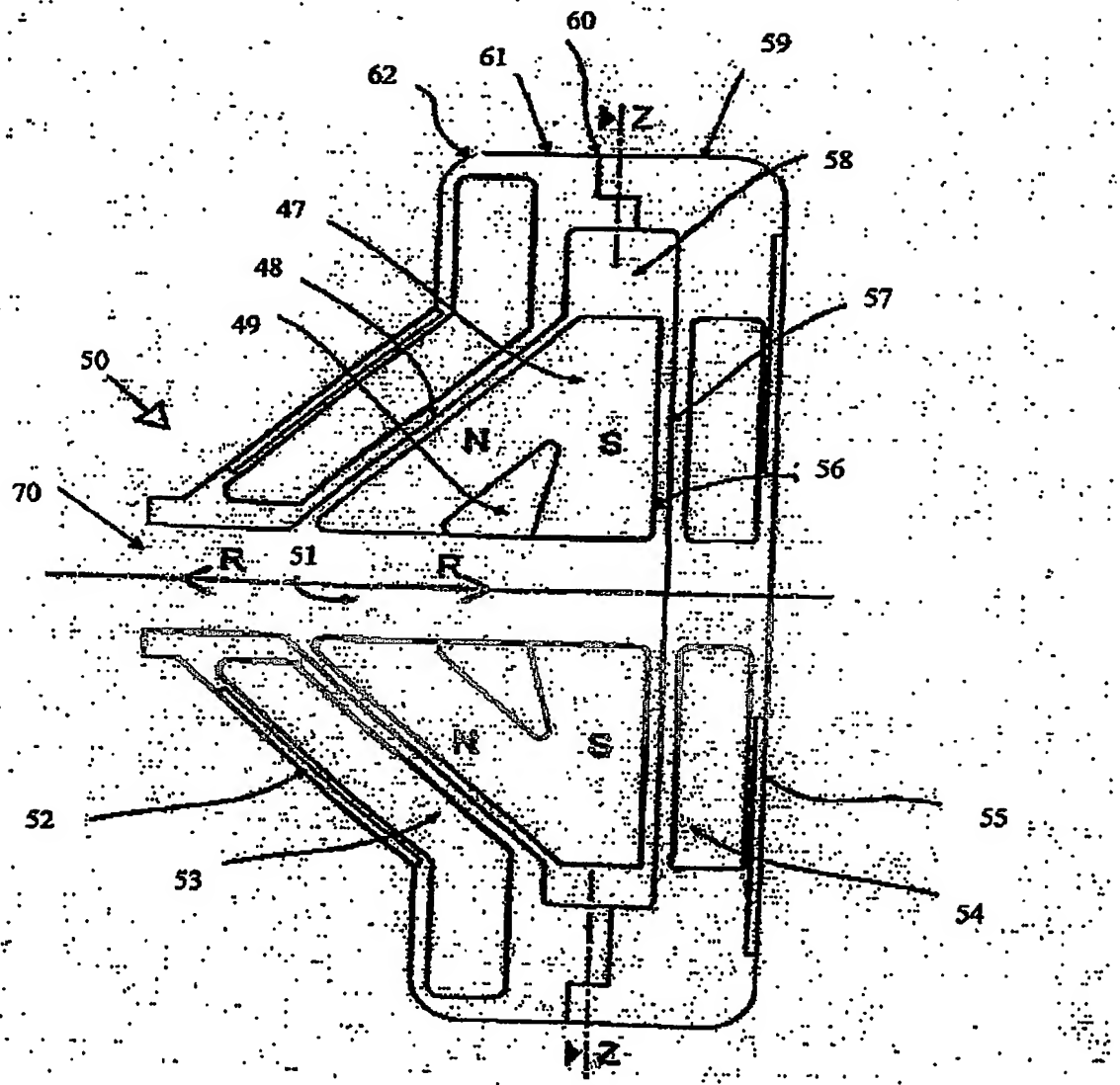

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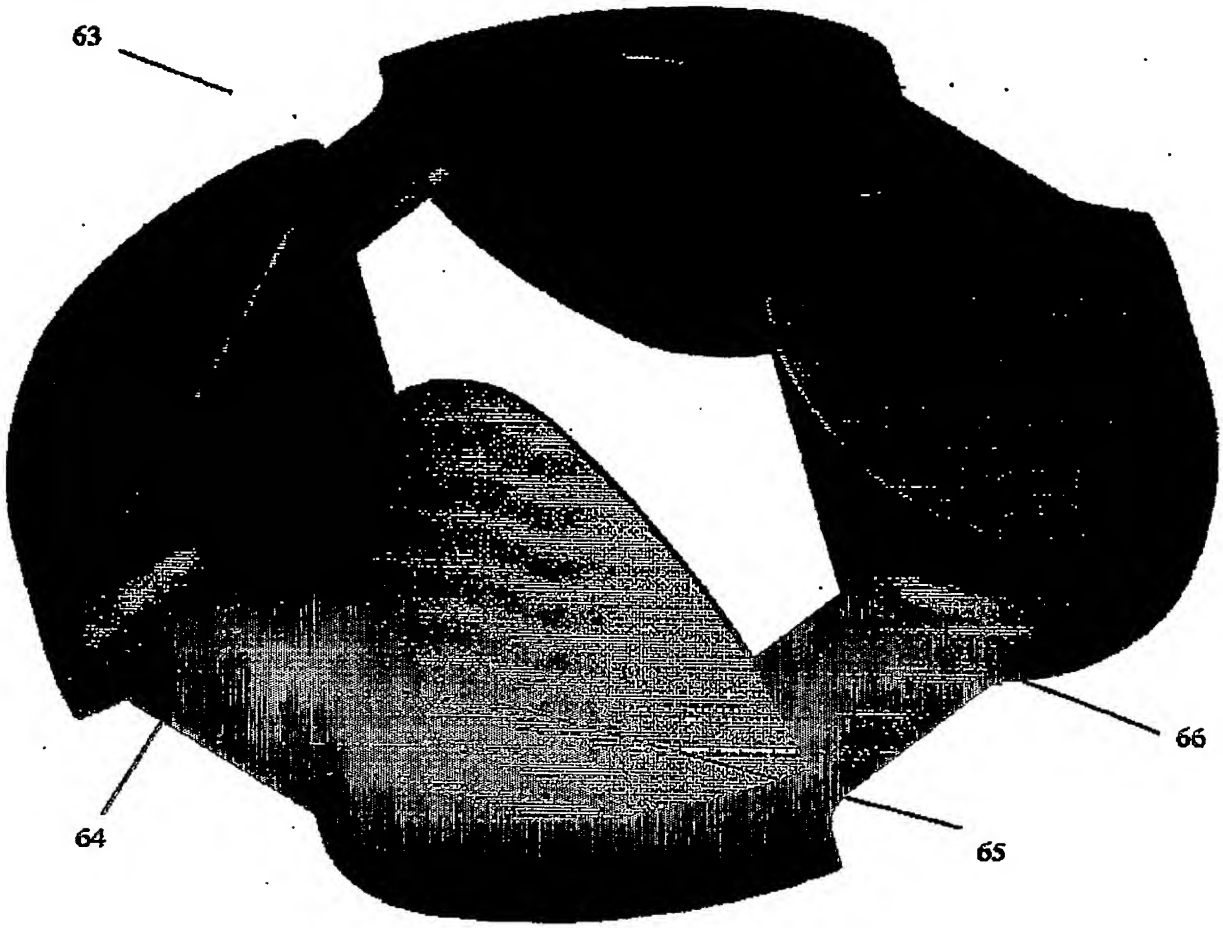

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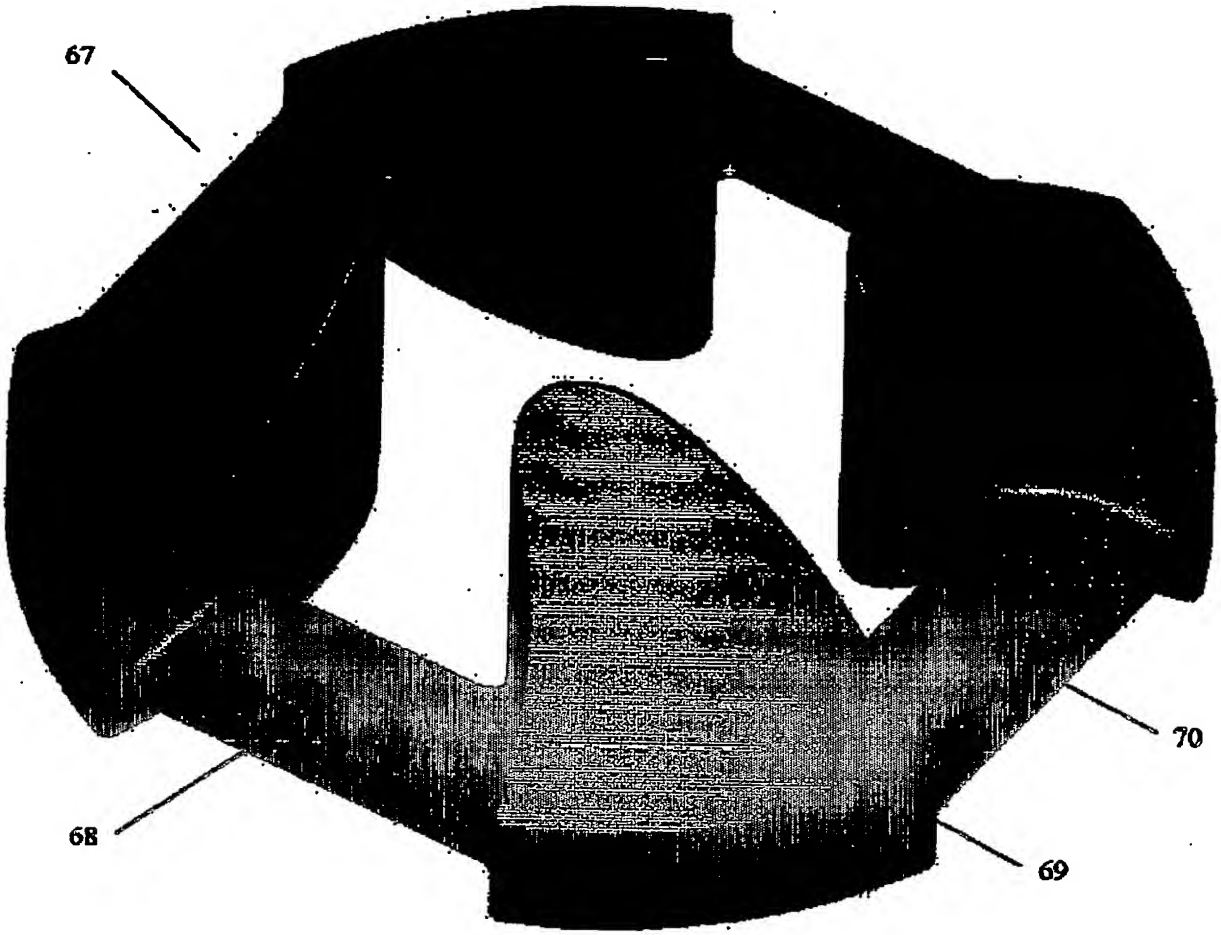

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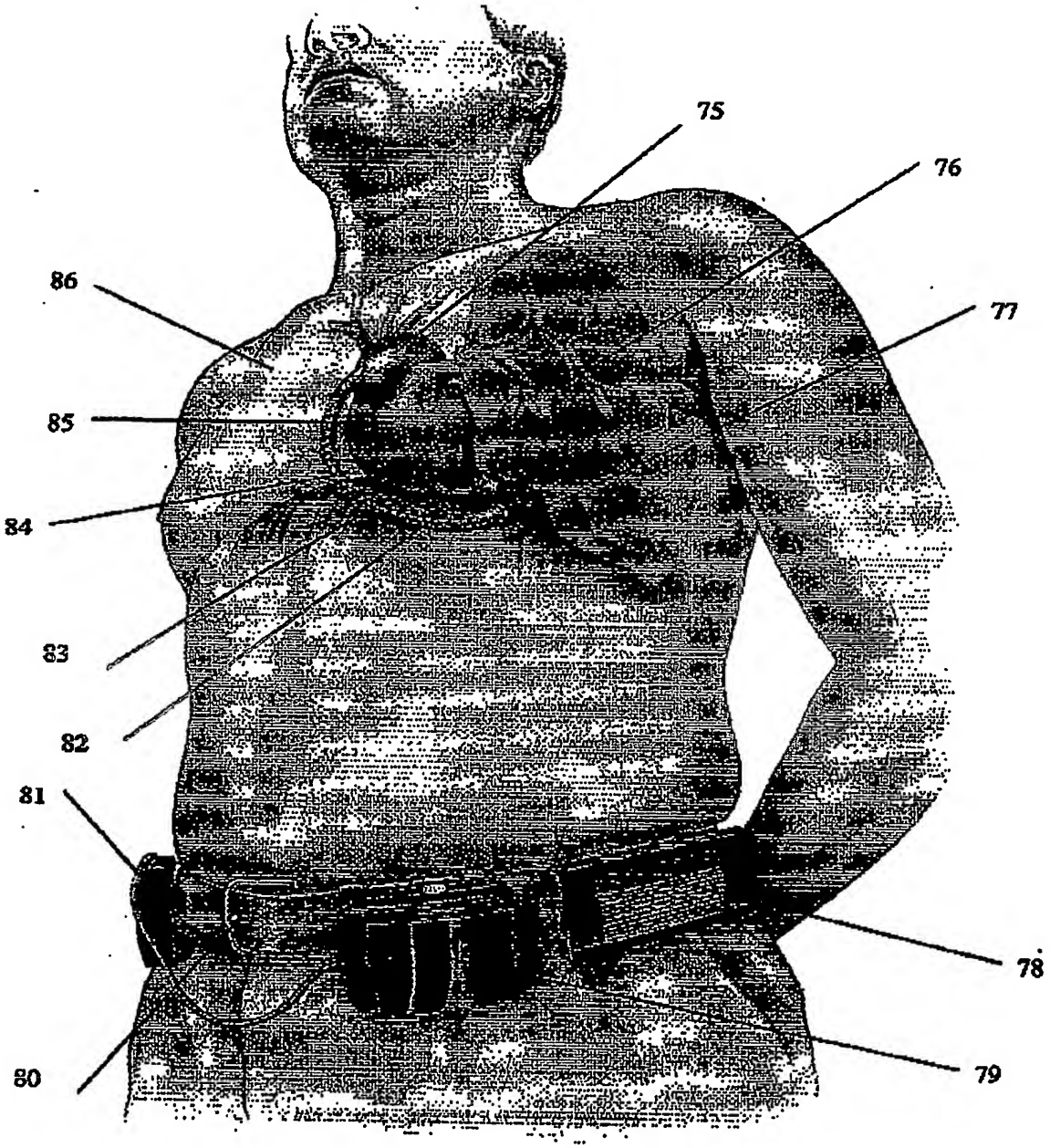


Figure 14 10

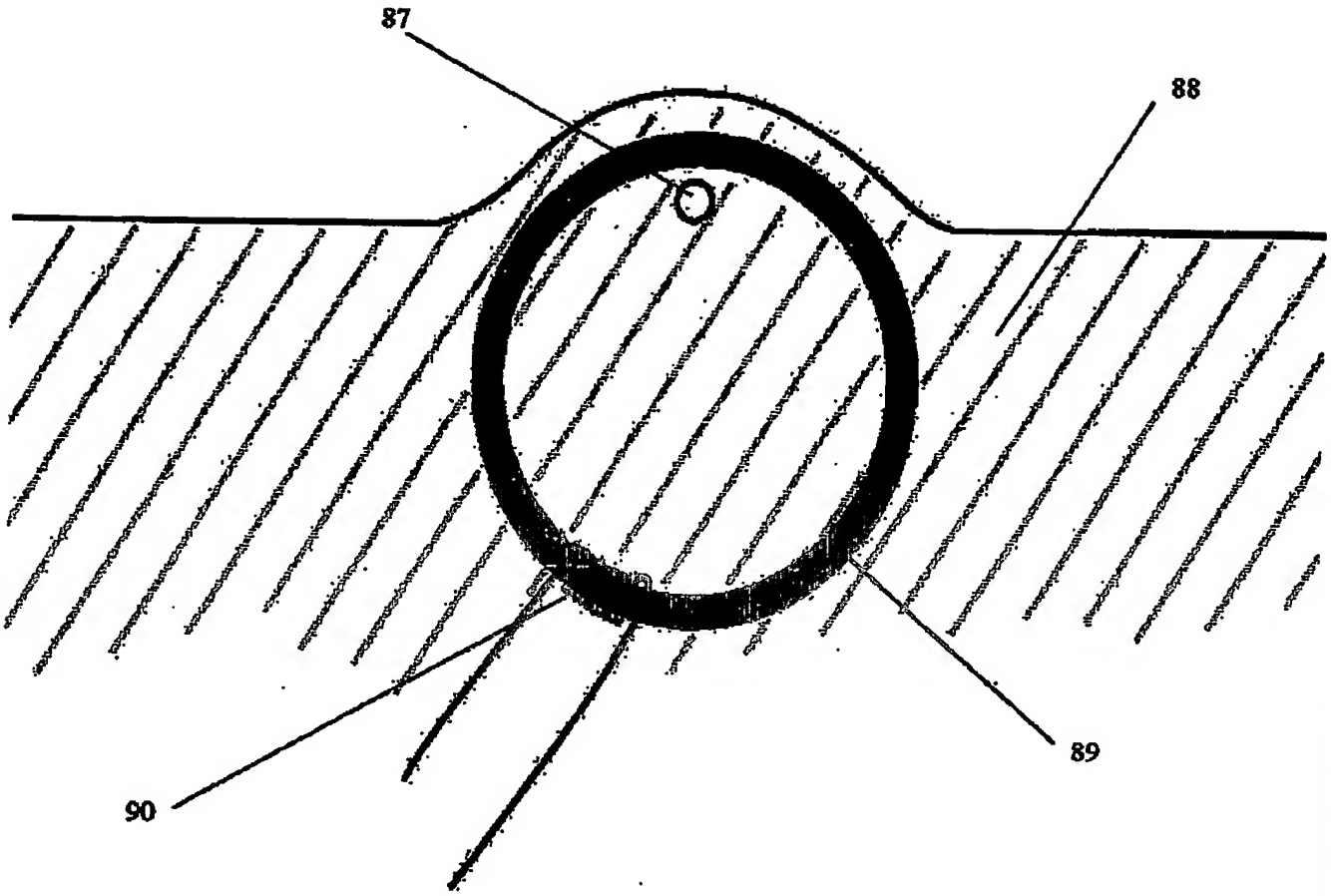


Figure 12 11

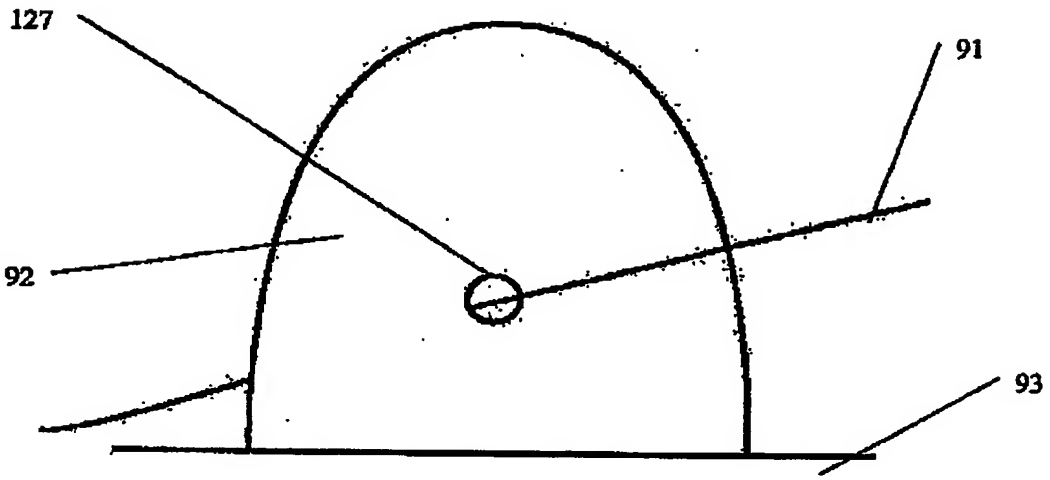


Figure 13

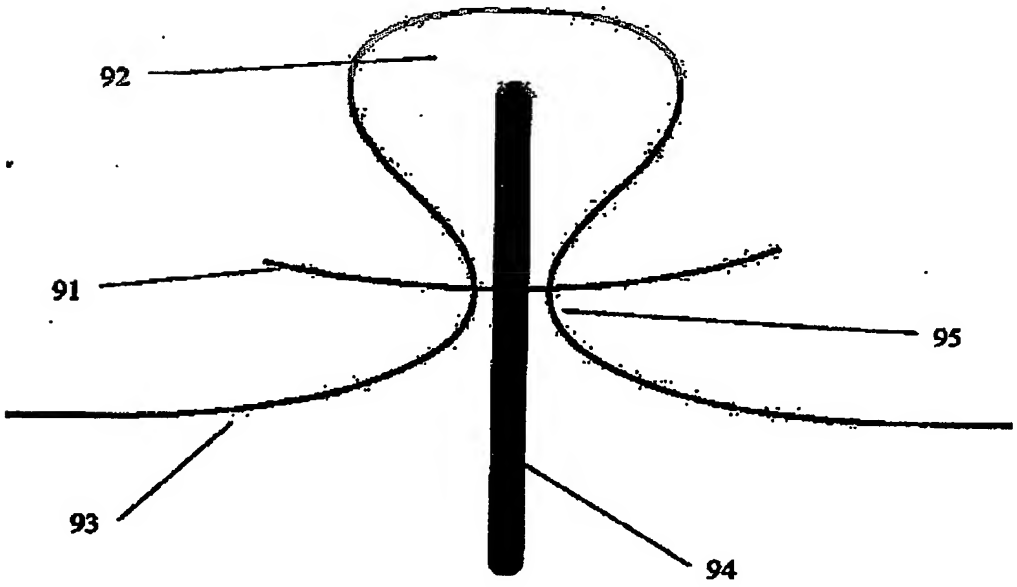
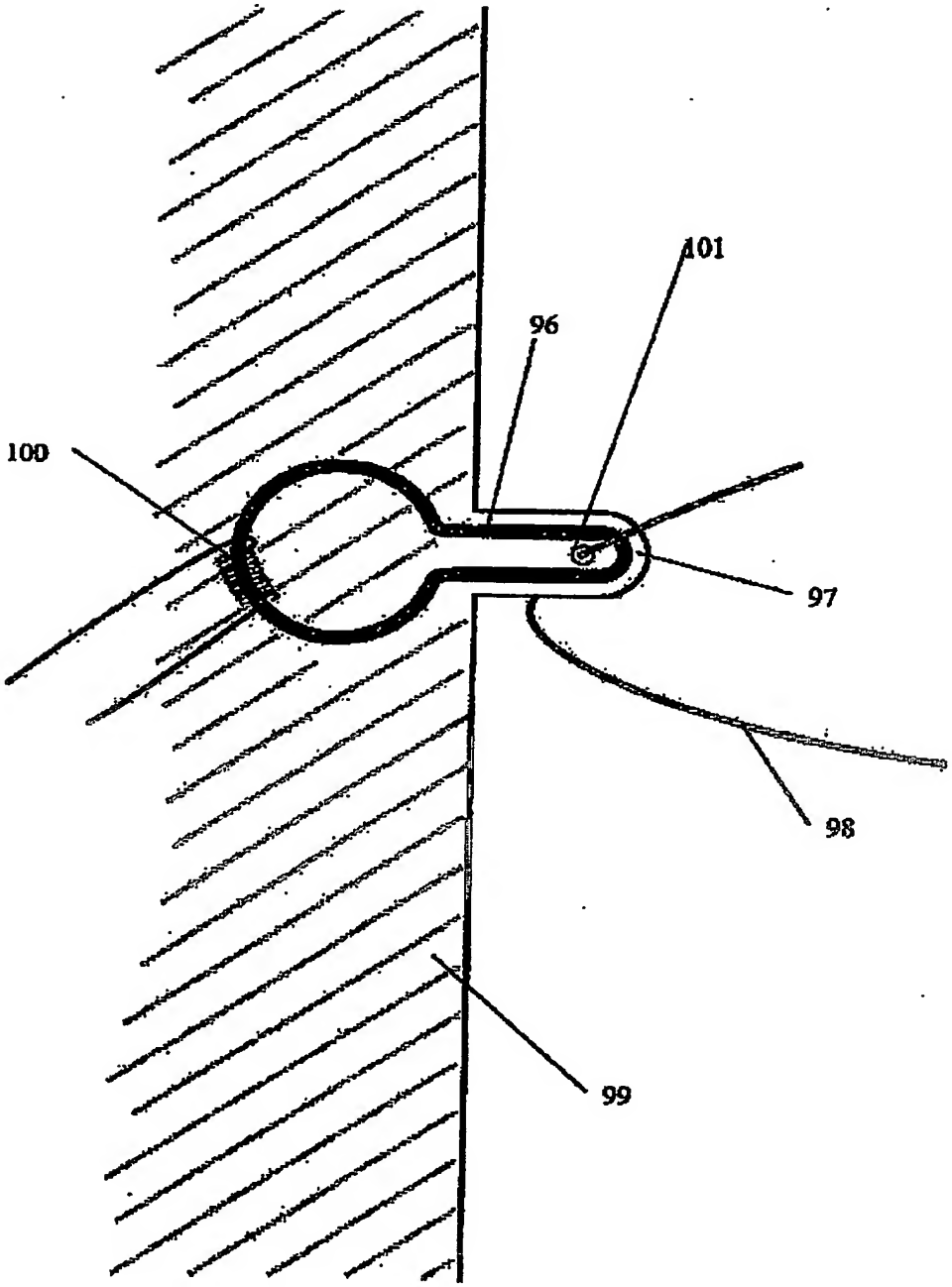


Figure ~~14~~ 13



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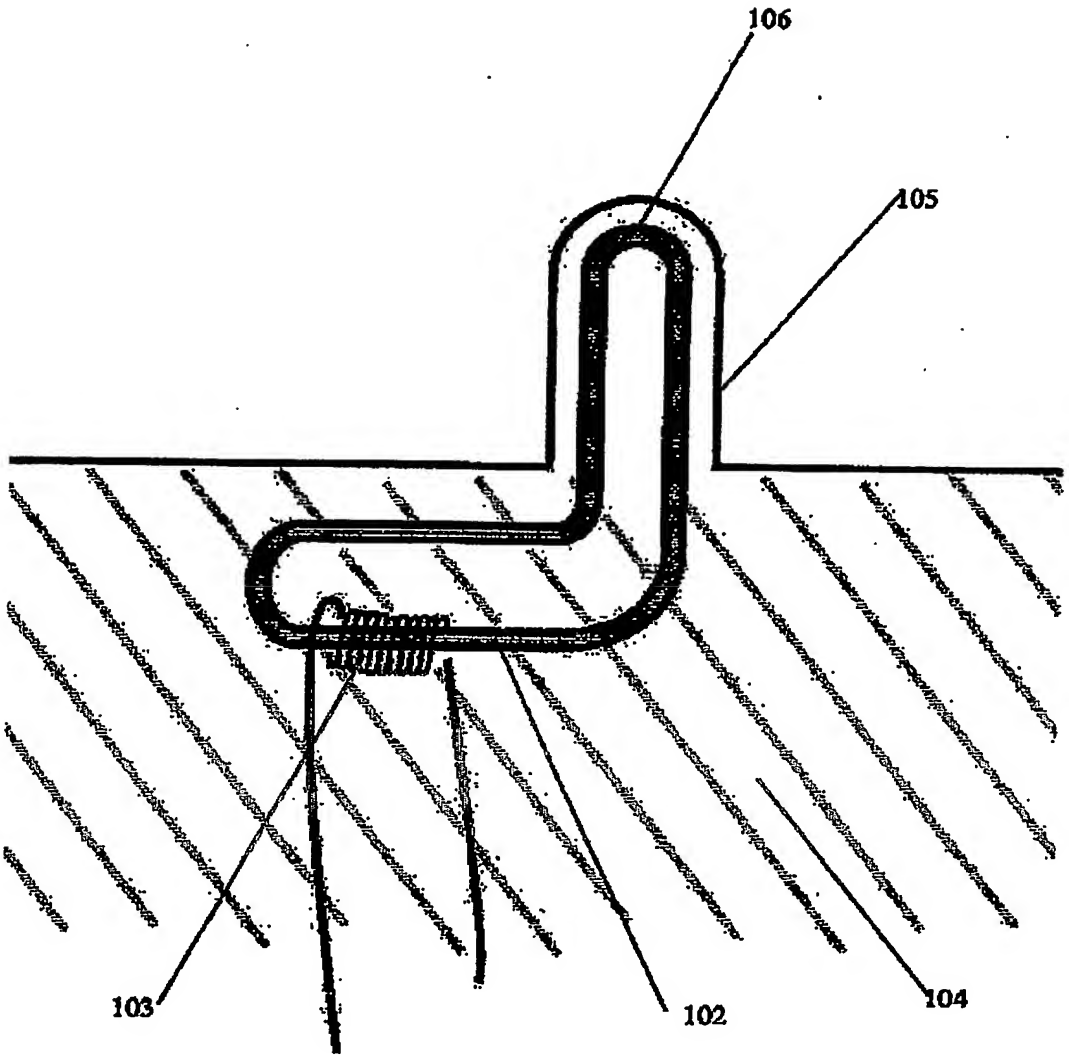
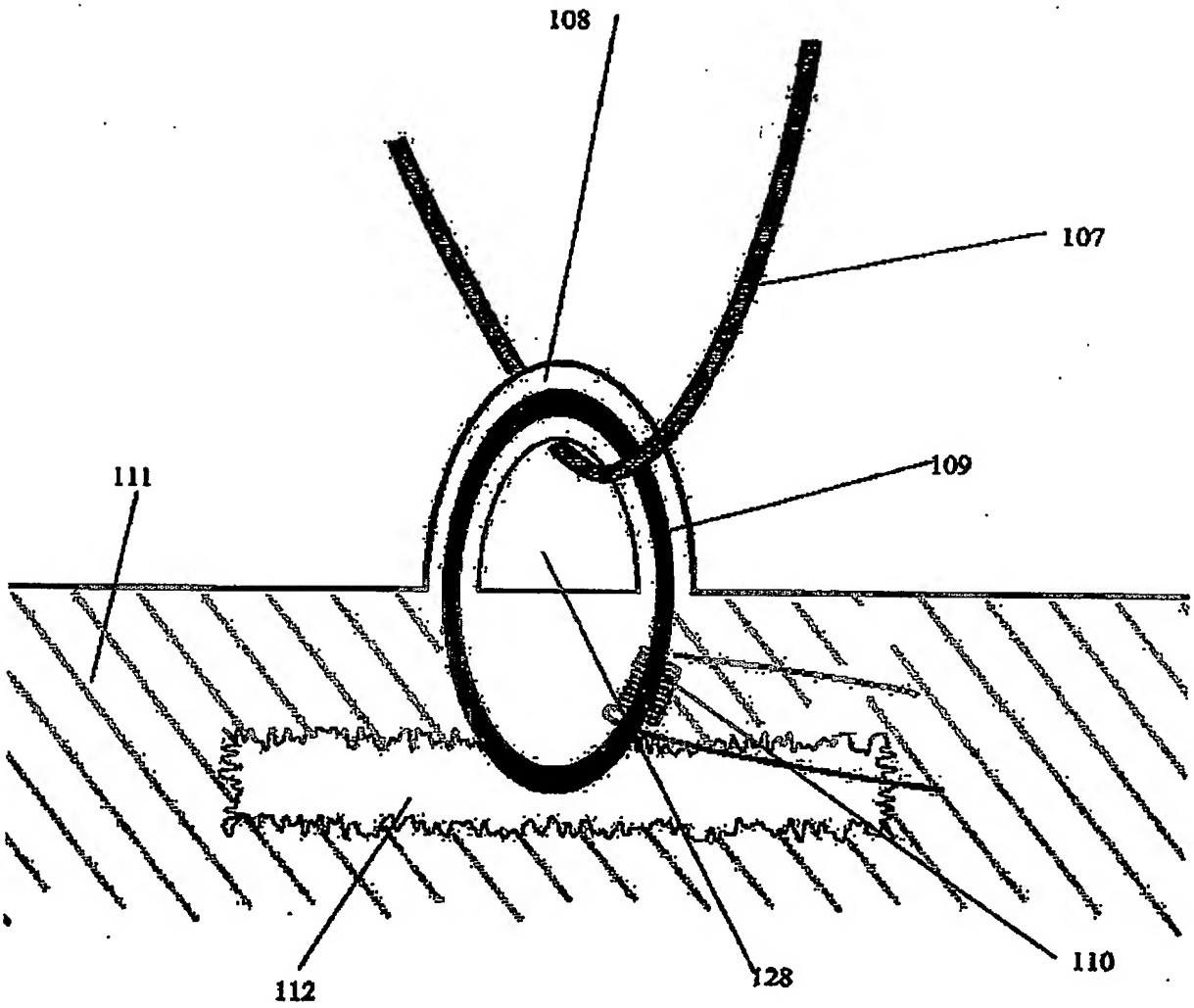


Figure 16 / 5



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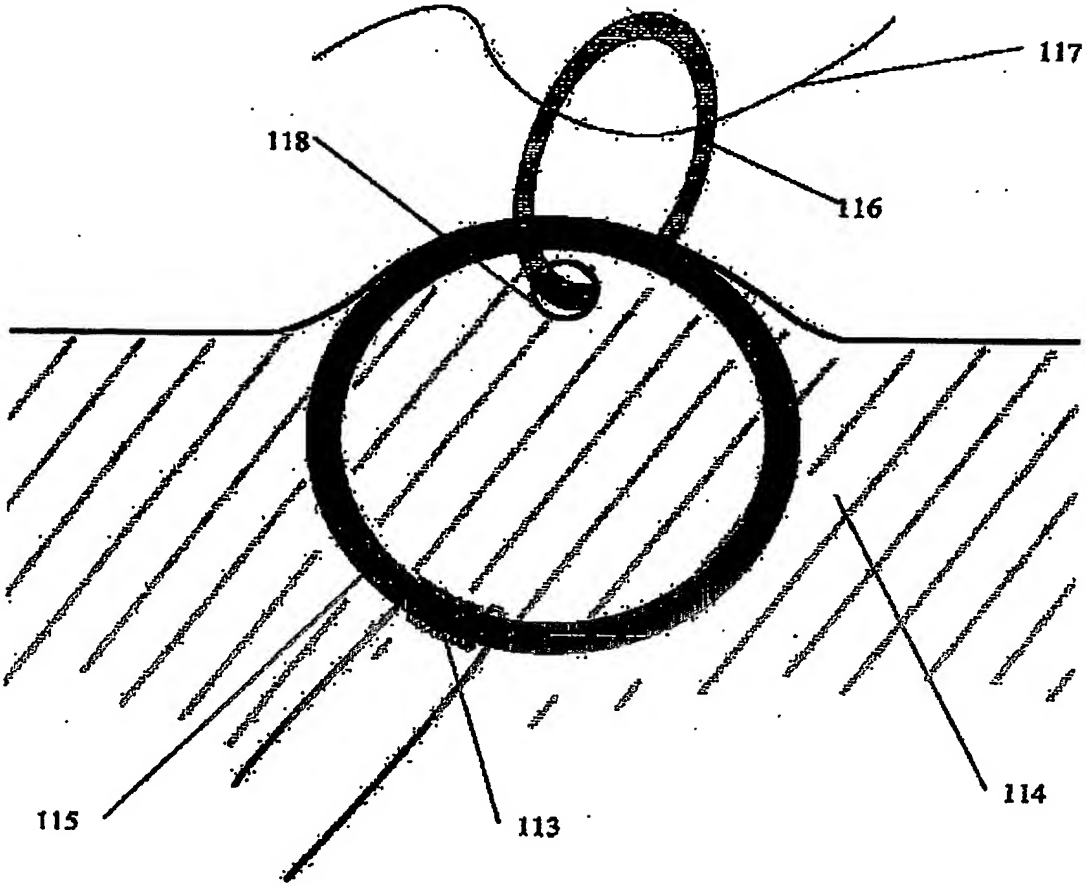

Figure 18, 17

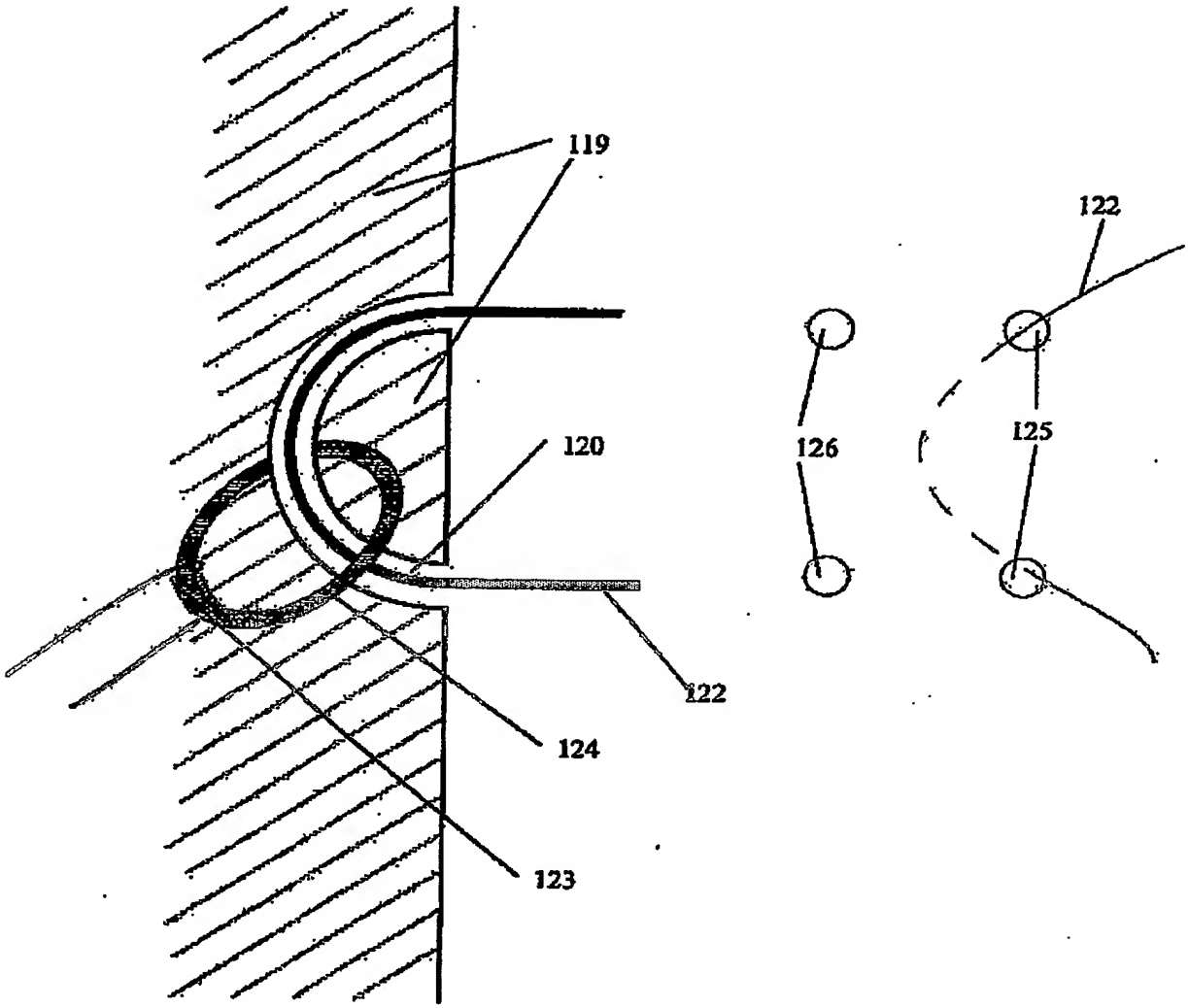

Figure 18